


TEST REPORT

MEDICAL ELECTRICAL EQUIPMENT

Equipment / Product	<i>LCD type Computer</i>		
Name and address of the applicant	<i>Advantech Co., Ltd. 4F, No. 108-3, Ming-Chuan Road. Shing-Tien City, Taipei TAIWAN, R.O.C.</i>		
Name and address of the manufacturer	<i>Advantech Co., Ltd. 4F, No. 108-3, Ming-Chuan Road., Shing-Tien City, Taipei TAIWAN, R.O.C.</i>		
Name and address of the factory	<i>Advantech Co., Ltd. Fl. 7, NO. 1, Lane 169, Kang-Ning Street Xi-Zhi Town, Taipei Hsien TAIWAN, R.O.C.</i>		
Trade mark	<i>ADVANTECH</i>		
Model/type	<i>PPC-xyyM (Explanation for xyy on page 3 in this report)</i>		
Rating and principal characteristics	<i>100-250Vac, 3A, 50/60Hz, Class I equipment</i>		
Serial no			
Test sample(s) received, date	<i>24. oct. - 2000</i>		
Tested in the period, dates	<i>Oct. -Nov. - 2000</i>		
Tested according to	IEC 60601-1 (2 ed 1988) + Amend. 1 (1991) + Amend. 2 (1995) + Corrigendum (June 1995) MEDICAL ELECTRICAL EQUIPMENT - Part 1: General requirements for safety		
Result of testing	<i>The equipment complies with the above mentioned standards.</i>		
The test results relate only to the sample(s) tested.			
Name and address of the testing laboratory	 P.O. BOX 73 BLINDERN, N - 0314 OSLO, NORWAY		Telephone (+47) 22 96 03 30 Fax (+47) 22 96 05 50
Tested by			
	Signature <i>Johny Giang</i>		date
Verified by			
	Signature <i>Frank Skarpsno</i>		date
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Verdicts are placed in the column to the right.: **P** = Pass, **F** = Fail, **N** = Not applicable, $\frac{3}{4}$ = Considered/Information.

Due to Nemko's computerised handling of test reports the layout of this form is modified compared to the original TRF published by EMEDCA; 1992-12-01. The content fully covers the original TRF.

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Issue Nemko 97-09-05

	DESCRIPTION OF EQUIPMENT UNDER TEST:	
	<i>The PPC-150 panel PC is a multimedia Pentium MMX processor-based computer that is designed to serve as a human machine interface (HMI) and as a desktop computer. It is a PC-based system with 15" color TFT LCD display, on-board PCI Ethernet controller, multi-COM port interfaces and a 16-bit audio controller. With built-in CD-ROM drive, floppy drive and PCMCIA expansion sockets.</i>	
	NAME AND ADDRESS OF PRODUCTION-SITES (FACTORIES):	
	<i>See front page.</i>	
	INFORMATION ABOUT THE STANDARDS / DOCUMENTS CONSIDERED:	
	<i>EN 60601-1 (1990) + A1 (1993) + A2 (1995) +A13 (1996) + Corrigenda (July 1994).</i>	
	<i>EMC standard : EN 60601-1-2 (1993)</i>	
	TESTED ACCORDING TO NATIONAL REQUIREMENTS FOR THE FOLLOWING COUNTRIES:	
	LIST OF APPENDIXES / ENCLOSURES TO THE TEST REPORT:	
	<i>See page 4.</i>	

SUMMARY OF TESTING		
<p>Evaluation of Results</p> <p>If not explicitly stated otherwise in the standard, the test is passed if the measurement value is equal to or below the limit line, regardless of the uncertainty of the measurement. If the measurement value is above the limit line, the test is not passed - ref. IEC 60EE/CTL (sec) 056/94 (CLT = Committee of Testing Laboratories).</p> <p>The instrument accuracy is within limits agreed by this committee (ref. Nemko proc P227):</p> <p><i>Models PPC-xyyM</i> <i>where xx can be 12 or 15 for 12" LCD or 15" LCD</i> <i>where y can be 0-9</i></p> <p><i>This computer uses adaptor (Skynet, Model SNP-8086-M which has CB)</i></p>		
Clause	Remarks	Information/Comments

LIST OF ATTACHMENTS PROVIDING FURTHER INFORMATION ON THE EQUIPMENT TESTED AND THE TEST METHODS			
The following attachments are added to this TRF or kept in file at the Testing Station mentioned at the cover page:			
<p>Statements on calibrations and measurement uncertainties (where relevant) of the measurement and test equipment as identified throughout this TRF:</p> <p>Calibration All instruments used in the tests given in this report are calibrated and traceable to international standards. Further information about tractability will be given on request.</p> <p>Measurement uncertainties Measurements uncertainties are calculated for all instruments and instruments set-ups given in this report. Calculations are based on the principles given in the standard EA -4/02 (Dec. 1999). Further information about measurements uncertainties will be given on request</p>			
Document title/identification:	<i>Kept in file at Nemko; P31000</i>	ATT. No.:	<i>Not attached</i>
List of worksheets which describe measurement procedures or test methods where practicable:			
Document title/identification:	<i>Kept in file at Nemko; P31000</i>	ATT. No.:	<i>Not attached</i>
List of equipment or units tested and/or accompanying units and accessories (in case not all individual units can be mentioned on the front-page):			
Document title/identification:	<i>See summary of testing in this report.</i>	ATT. No.:	<i>Not attached</i>
Technical design documents of components having basic, supplementary or reinforced insulation (e.g. transformer specification mentioning the insulation class of the insulation materials applied - A to H):			
Document title/identification:	<i>Kept in file at Nemko</i>	ATT. No.:	<i>Not attached</i>
Description of safety systems (specifying for example safety circuits, redundant circuits, double circuits, hardware/software safety measures, temperature controls, etc.):			
Document title/identification:	<i>Kept in file at Nemko</i>	ATT. No.:	<i>Not attached</i>

PERSONNEL - INITIALS USED THROUGHOUT THIS TRF			
Initials:	Full name:	Signatures:	
	This Part 1 TRF contains 73 pages, numbered from 1 to 73 .		
	This TRF contains photographs. Attachment no. 1		
	Attachment no. 2. EMC report no. 200045135		

3	GENERAL REQUIREMENTS		
3.1	EQUIPMENT when transported, stored, installed, operated in NORMAL USE and maintained according to the instructions of the manufacturer, causes no SAFETY HAZARD which could reasonably be fore- seen and which is not connected with its intended application in NORMAL CONDITION and in S.F.C.	<i>The equipment causes no hazards when used according the manufacturers instructions.</i>	P
3.4	An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safety is obtained.	<i>No alternative construction.</i>	N

5	CLASSIFICATION		
5.1	Type of protection against electric shock.	<i>Class I equipment.</i>	
5.2	Degree of protection against electric shock.	<i>No applied part. This is a Personal Computer. As the equipment is not intended to be connected to the patient and does not have any patient applied parts, it is not marked with the type B applied part symbol.</i>	
5.3	Classification of the equipment against ingress of liquids.	<i>Ordinary equipment.</i>	
5.5	Degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE	<i>The equipment is not an AP or APG category equipment.</i>	
5.6	Mode of operation.	<i>Continuous operation.</i>	

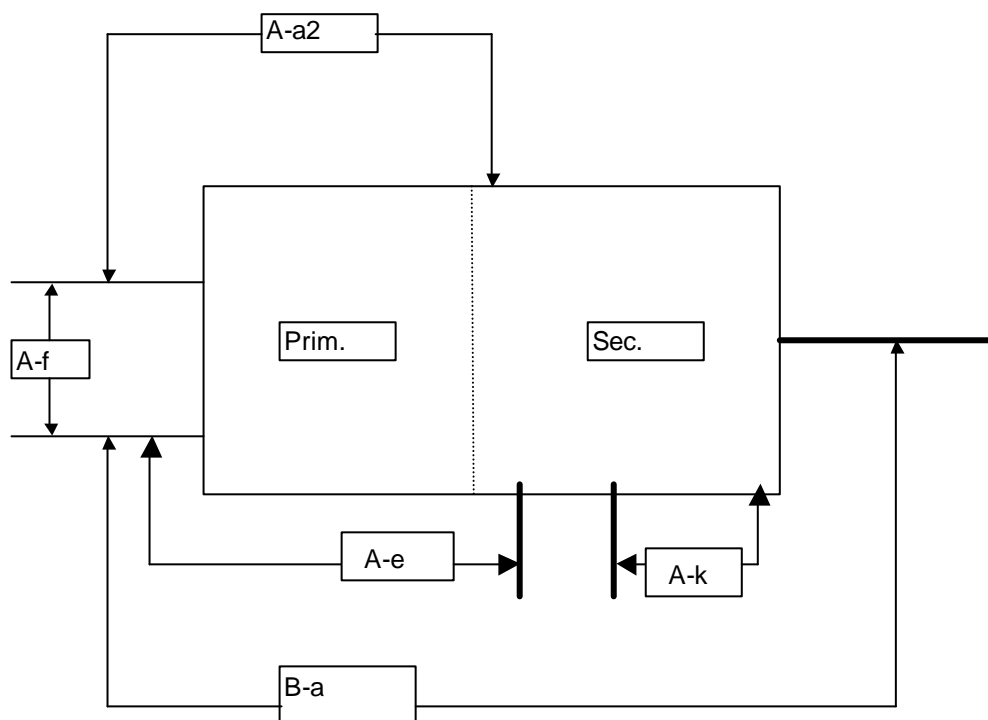
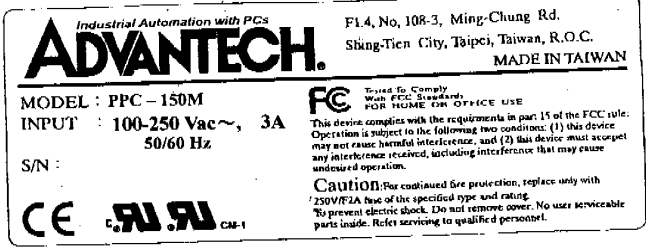
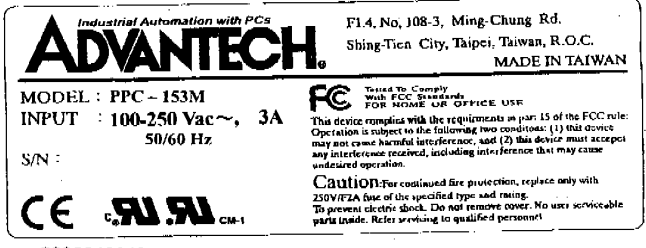
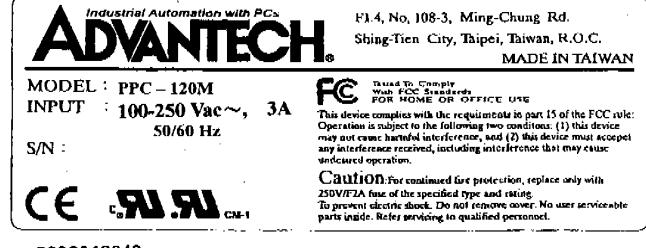
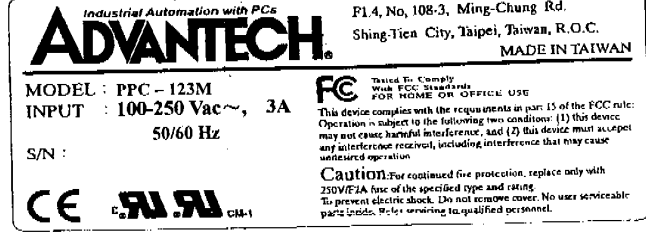




INSULATION DIAGRAM			
	Protection against electric shock - Block diagram of system	<i>Refer to table on next page.</i>	P
Drawing			
			
Comments			

TABLE TO INSULATION DIAGRAM ON PREVIOUS PAGE					
Distance (Test Refer to 20.1 + 20.2)	Insulation type Basic/Supplement./ Double/Reinforced Insulation	Maximum circuit voltage	Required distances (mm)		Dielectric strength test voltage Refer to 20.3
			Clearance	Creepage	
<i>A-a₂</i>	<i>Double/Reinforce.</i>	<i>250 V a.c.</i>	<i>5,0 mm</i>	<i>8,0 mm</i>	<i>4 000 V a.c.</i>
<i>A-k</i>	<i>Double/Reinforce.</i>	<i>250 V a.c.</i>	<i>5,0 mm</i>	<i>8,0 mm</i>	<i>4 000 V a.c.</i>
<i>A-e</i>	<i>Double/Reinforce.</i>	<i>250 V a.c.</i>	<i>5,0 mm</i>	<i>8,0 mm</i>	<i>4 000 V a.c.</i>
<i>A-f</i>	<i>Basic</i>	<i>250 V a.c.</i>	<i>1,6 mm</i>	<i>3,0 mm</i>	<i>1 500 V a.c.</i>
<i>B-a</i>	<i>Double/Reinforce.</i>	<i>250 V a.c.</i>	<i>5,0 mm</i>	<i>8,0 mm</i>	<i>4 000 V a.c.</i>
Comments					

6	IDENTIFICATION, MARKING AND DOCUMENTS	
6.1	Marking on the outside	<i>Example of marking label:</i>
6.1 a	Markings of Mains operated EQUIPMENT	<div data-bbox="762 412 1410 658">  </div> <div data-bbox="762 703 1410 949">  </div> <div data-bbox="762 994 1410 1240">  </div> <div data-bbox="762 1285 1410 1532">  </div>
6.1 b	Markings of Internally Powered EQUIPMENT	<i>Not applicable. Not internally powered equipment</i>
6.1 c	Markings of EQUIPMENT supplied from a specified power supply	<i>Not applicable.</i>
6.1 d	Minimum requirements if limited space for marking	<i>Not applicable.</i>
6.1 e	Name and/or trademark of the manufacturer or supplier	<i>See front page</i>
6.1 f	Model or type reference	<i>See front page</i>
6.1 g	Rated supply voltage(s) or voltage range(s) Number of phases Type of current	<i>100-250 V ~ Single phase a.c.</i> <i>3A</i>
6.1 h	Rated frequency or rated frequency range(s) in Hz	<i>50/60 Hz.</i>

6.1 j	Rated power input (VA, W or A)	3A	P
6.1 k	Power output of auxiliary mains socket outlets	No	N
6.1 l	Class II symbol	Not applicable. Not Class II.	N
	Symbol for degree of protection with respect to harmful ingress of water according to EN 60529 (IPX0 not required to be marked)	Ordinary equipment. IP X0.	N
	Symbol for protection against electric shock:	Personal Computer. As the equipment is not intended to be connected to the patient and does not have any patient applied parts, it is not marked with the type B applied part symbol.	N
6.1 m	Mode of operation (if no marking, suitable for continuous operation)	Continuous operation.	P
6.1 n	Types and rating of external accessible fuses	No external fuses.	N
6.1 p	Rated output voltage and current or power, output frequency (where applicable)	No auxiliary mains socket outlets.	N
6.1 q	Symbol for physiological effect(s):	Not applicable. No need for marking.	N
6.1 r	Anaesthetic-proof symbol:	Not of category AP or APG.	N
6.1 s	High voltage symbol:	Symbol 6 of table DII, Dangerous voltage  is used.	N
6.1 t	Special cooling requirements	Fan used	P
6.1 u)	Limited mechanical stability	10°	P
6.1 v	Protective packing requirement(s). Marking(s) for unpacking safety hazard(s)		P
6.1 y	Earth terminals:	Appliance inlet used	P
6.1 z	Removable protective means		P
	Durability of markings	Tested with a cloth of rack soaked with, in turn, water, methylated spirit and isopropyl alcohol. The sample label withstood the test.	P
6.2	Marking on the inside		
6.2 a	Marking clearly legible		P
	Nominal supply voltage of permanently installed equipment marked inside or outside of equipment	Not permanently installed equipment	N
6.2 b	Maximum power loading of heating elements or lamp holders for heating lamps clearly and indelibly marked near or in the heater	No heating elements used	N
	Heating elements or lamp holders for heating lamps not intended to be changed by operator and which can be changed only with the use of a tool, have at least an identifying marking referring to information stated in the accompanying documents		N

6.2 c	High voltage parts:	<i>Symbol 6 of table DII, Dangerous voltage  is used.</i>	P
6.2 d	Type of battery and mode of insertion (if applicable) marked (see Sub-clause 56.7 b)	<i>Back up battery. Type M4T28-BR12SH1, rating 5V, 50mAh</i>	P
	Batteries not intended be changed by operator and which can be changed only with use of tool have at least marking referring to information in accompanying documents		P
6.2 e	Fuse type and rating or reference stated	<i>GBP, 12A, 250Vac</i>	P
6.2 f	Protective earth terminal marked 		P
6.2 g	Functional earth terminal marked 	<i>Not applicable.</i>	N
6.2 h	Terminals for supply neutral conductor in permanently installed equipment marked (N)	<i>Not applicable.</i>	N
6.2 j	Markings required in Sub-clause 6.2 f, h, k and l		P
6.2 k	The supply connections are clearly marked adjacent to the terminals or in accompanying documents (for small equipment)		P
6.2 l	Statement for suitable wiring materials (at temperatures over 75°C) locates at or near the point of the supply connections and is clearly discernible after connection	<i>Not applicable.</i>	N
6.2 n	Capacitors and/or circuit parts are marked as required in Sub-clause 15 c	<i>Not applicable.</i>	N
6.3	Marking of controls and instruments		
6.3 a	Mains switch clearly identified. "On" and "off" positions marked or otherwise indicated		P
6.3 b	Adequate indications of different positions of controls and other switches	<i>Not applicable.</i>	N
6.3 c	Adequate indication of the direction of setting devices if change of setting of a control could cause a safety hazard		N
6.3 f	Functions of operator controls and indicators identified		N
6.3 g	Numeric indications of parameters are in SI units according to ISO 1000. Units outside the International System as specified		N
6.4	Symbols		
6.4 a	Marking symbols compliance with appendix D, where applicable		P

6.4 b	Symbols for controls and performance conform to IEC 60 878, where applicable	<i>Not applicable.</i>	N
	Durability of marking symbols	<i>Tested in Clause 6.1.</i>	P
6.5	Colours of insulation of conductors		
6.5 a	Protective earth conductor has green/yellow insulation		P
6.5 b	All insulations of internal protective earth conductors are green/yellow, at least at the terminations of the conductors		P
6.5 c	Only protective earth-, functional earth-, potential equalisation and inside earthing conductors (cf. 6.5 b) are green/yellow	<i>Not used</i>	N
6.5 d	Colour of neutral conductor: light blue according to IEC 60 227 or 245		P
6.5 e	Colours of phase conductors in power supply cord according to IEC 60 227 or 245		P
6.5 f	Additional protective earthing in multi-conductor cords are marked green/yellow at the ends of the additional conductors		P
6.6	Identification of medical gas cylinders and connections		
6.6 a	Identification of content in accordance with ISO/R32	<i>No medical gas used</i>	N
6.6 b	Identification of connection point that errors are avoided when a replacement is made		N

6.7	Indicator lights and push-buttons		
6.7 a	Colour red only used for warning of danger or/and need for urgent action. Dot-matrix/alphanumeric displays not considered to be indicator lights	<i>No colour red used</i>	N
6.7 b	Colours of unilluminated push-buttons. Colour red only used in case of emergency		N
Location	Meaning of indicator lights	Illuminated push-button (see IEC 60 73)	Colour
—	—	—	—
—	—	—	—
6.8	Accompanying documents		
6.8.1	Equipment is accompanied at least by		
	- instructions for use	<i>User Manual</i>	P
	- technical description	<i>User Manual</i>	P
	- an address to which the user can refer	<i>User Manual</i>	P
	All applicable classifications specified in Clause 5 are included in instructions for use and technical description	<i>User Manual</i>	P
	markings in Sub-clause 6.1 included in accompanying documents if not permanently affixed to equipment		P
	Warning statements and explanations of warning symbols are provided in accompanying documents	<i>Not used</i>	N
	Language of accompanying documents	<i>English. Will be in the language required for the market where the equipment is intended to be sold.</i>	P

6.8.2	Instructions for use		
6.8.2 a	General information		
	Necessary information to operate the equipment		P
	Explanation of the function of controls, displays and signals		P
	Sequence of operation		P
	Connection and disconnection of detachable parts and accessories	<i>Detachable power supply cord</i>	P
	Replacement of material which is consumed during operation	<i>Not applicable.</i>	N
	Indications of recognised accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	<i>Not applicable.</i>	N
	Cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	<i>User Manual</i>	P
	Information about safe performance of routine maintenance		P
	Information about preventive inspection and maintenance to be performed by other persons		P
	Meanings of figures, symbols, warning statements and abbreviations on equipment explained in the instructions for use		P
	Instruction for use states the function and intended application of equipment		P
	Instructions for use provide user with information regarding potential electromagnetic or interference and advice how to avoid such interference	<i>Not applicable.</i>	N
6.8.2 c	Signal output and signal input parts		
	Signal output or signal input parts intended only for connection to specified equipment stated in instruction for use	<i>Not applicable.</i>	N
6.8.2 d	Cleaning, disinfection and sterilisation of parts in contact with the patient		
	Details about cleaning or disinfection or sterilisation methods that may be used for equipment parts which come into contact with the patient during normal use given in instruction for use	<i>Properly described.</i>	P

6.8.2 e	Mains operated equipment with additional power source		
	A warning statement referring to the necessity for periodical checking or replacement of an additional power source	<i>Not applicable. No used of additional power source</i>	N
	If Class I equipment a statement saying that where the integrity of the external protective conductor in the installation or its arrangement is in doubt, equipment shall be operated from its internal electrical power source	<i>Not applicable.</i>	N
6.8.2 f	Removal of primary batteries (i.e. not rechargeable batteries):	<i>No primary batteries used</i>	
	Instruction for use contains a warning to remove batteries if equipment is not likely to be used for some time ,unless no risk of safety hazard		N
6.8.2 g	Rechargeable batteries:	<i>Not rechargeable batteries</i>	
	Instructions to ensure safe use and adequate maintenance		N
6.8.2 h	Equipment with a specified power supply or battery charger:		
	Instructions for use identify power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	<i>Not applicable.</i>	N
6.8.2 j	Instructions for use identify risks associated with disposal of waste, residues etc. and of equipment/accessories at end of their lives. Further it provides advice on minimising these risks	<i>Not applicable.</i>	N
6.8.3	Technical description		
6.8.3 a	General		
	Technical description provides all data essential for safe operation including data in Sub-clause 6.1 and all characteristics of the equipment	<i>The Technical and Service Manual is well written and contains all necessary information required.</i>	P
	A statement whether particular measures or particular conditions are to be observed for installing equipment and bringing equipment into use	<i>Not applicable.</i>	N
6.8.3 b	Replacement of fuses and other parts :		
	Required type and rating of fuses utilised in the mains supply circuit external to permanently installed equipment	<i>Not applicable. Not permanently installed equipment</i>	N
	Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	<i>Not applicable.</i>	N

6.8.3 c	Circuit diagrams, component part lists, etc.:		
	The technical description contains a statement that the supplier will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, etc. in order to assist user in case of necessary reparations	<i>Not applicable.</i>	N
6.8.3 d	Environmental conditions for transport and storage:		
	The technical description contains a specification of the permissible environmental conditions for transport and storage		P
	The above said specification also repeated on the outside of the packaging		P

7	POWER INPUT				
7.1	Steady state current or power input does not exceed the marked rating by more than specified	<i>Input power: 100-250Vac, 3A, 50/60Hz</i> <i>Deviation: (measured-rated)*100/rated = %</i>			P
	Equipment:	<i>N3635</i>			
	Initials Tester / Date:	<i>JohnnyG / 10-2000</i>			
Power input	Function	$U_{Nlower} = 90 \text{ V}$	$U_N = 170 \text{ V}$	$U_{Nupper} = 275 \text{ V}$	
Input current	Normal operation (A)	<i>1,4/1,4</i>	<i>0,98/0,98</i>	<i>0,6/0,6</i>	
	Standby (A)	—	—	—	
Input power	Normal operation (W)	<i>69/69</i>	<i>68/67</i>	<i>68/68</i>	
Input power	Normal operation (VA)	—	—	—	
Power factor	$\cos \varphi$	<i>0,54/0,54</i>	<i>0,48/0,47</i>	<i>0,40/0,41</i>	
Comments	<i>Power input rated is measured at both 50 and 60Hz. The 50Hz values are showed before “/” and the 60Hz is back. (Remark: #PPC-15yM-zT)</i>				

10	ENVIRONMENTAL CONDITIONS				
10.1	Equipment capable, while packed for transport and storage, of being exposed to environmental conditions as stated by manufacturer (see 6.8.3 d)	<i>Considered OK.</i>			P
10.2	Operation of equipment according to specified environment and power supply	<i>Considered OK.</i>			P

13	GENERAL			
	Equipment so designed that risk of electric shock obviated as far as practicable (requirements as given in section three)	<i>Considered OK.</i>		P

14	REQUIREMENTS RELATED TO CLASSIFICATION			
14.1	Class I equipment			
14.1 a	Parts with Double Insulation	<i>Transformer</i>		P
	Parts with Reinforced Insulation	<i>Transformer</i>		P
	Parts with SELV-Voltage			N
	Parts with Protective Impedance			N
14.1 b	If the mains part of equipment specified for an external d.c. power source is isolated from accessible conductive parts by basic insulation only, a separate protective earth conductor is provided	<i>No external d.c. power source used</i>		N
14.2	Class II equipment			
14.2 a	Class II equipment is of one of the following types:	<i>Not applicable. Class I equipment</i>		N
14.2 b	If equipment is fitted with a device for changing over from class I to class II protection, the following requirements are fulfilled:	<i>Not applicable.</i>		N
	The change-over device indicates the selected class clearly			N
	A tool for change-over is necessary			N
	The equipment complies with all requirements for the selected class at any given time			N
	Class II position: The device interrupts the connection of protective earth conductor to equipment or changes it into functional earth conductor (compliance with 18.2)			N
14.2 c	Class II equipment provided with functional earth connections (cf. Sub-clause 18 k and l)			N
14.4	Class I and II equipment			
14.4 a	Equipment is provided with an additional protection according to the requirements of Class I or Class II equipment			P

14.4 b	No safety hazard develop, when a connection with the wrong polarity is made in equipment specified for power supply from an external d.c. power source (e.g. for use in ambulances)	<i>Not applicable.</i>	N
14.5	Internally powered equipment		
14.5 b	Equipment also having means of connection to supply mains complies also with requirements for Class I or II while so connected	<i>Not applicable.</i>	N
14.6	Types B, BF and CF applied parts		
14.6 c	Applied parts suitable for direct cardiac application are of type CF	<i>Not applicable.</i>	N

15		LIMITATION OF VOLTAGE AND/OR ENERGY										
15 b	Equipment with mains plug so designed that the voltage 1 sec. after disconnection does not exceed 60 V											P
	Interference suppression capacitors											P
	Capacitance between each line and protective earth. Measured value	3300pF										P
	Equipment:	N2843										
	Initials Tester / Date:	JohnnyG / 10-2000										
	Maximum residual voltage in the mains plug 1 second after disconnection (measured in the least favourable position of the on-off switch, if any):											
	Remark: pins 1 and 2 are Line and Neutral supply pins. Note! PE is equal to enclosure.											
Measurement no.	1	2	2	4	5	6	7	8	9	10		
Voltage between pins 1 and 2 (Limit 60 V)	14	14	14	14	14	14	14	14	14	14		
Voltage between pin 1 and PE (Limit 60 V)	14	14	14	14	14	14	14	14	14	14		
Voltage between pin 2 and PE (Limit 60 V)	14	14	14	14	14	14	14	14	14	14		
15 c	Accessible live parts of capacitors or related circuits having a residual voltage above 60 V does not have a residual energy above 2 mJ (see 15 c below)	Not applicable.										N
	A non-automatic discharging device is included and marked											N
	Equipment:											
	Initials Tester / Date:	/										
Capacitor and its location	Working voltage (V)	Capacitance value (mF)		Residual voltage (V)		Residual energy (mJ)						

16	ENCLOSURES AND PROTECTIVE COVERS			
16 a	Protection against contact with live parts.			P
	- and with parts which can become live in single fault conditions			P
	Instruction for use instructs operator not to touch such parts and the patient simultaneously	<i>Not applicable. No such parts</i>		N
	Equipment:	Standard test finger : Our ref. N 2489		
	Initials Tester / Date:	<i>JohnyG / 10-2000</i>		
Location of opening		Test result finger		
<i>Back of equipment</i>		<i>OK</i>		
16 b	Check of openings in top covers with the vertical suspended test rod	<i>No openings in the top covers</i>		N
16 c	Conductive parts of actuating mechanism of electrical controls after the removal of handles, knobs, levers etc. have either resistance to the protective earth terminal max. 0.2 ohms or the separation from live parts complies with 17 g	<i>Not applicable.</i>		N
16 d	Protection of contact with internal parts of the equipment with a circuit voltage exceeding 25 V a.c. or 60 V d.c. which cannot be disconnected from the supply by external mains switch or plug device	<i>Not applicable.</i>		N
	Equipment:			
	Initials Tester / Date:			
Location of part		Covering	Warning notice	Remarks
16 e	Protective enclosures are removable only with the aid of tool or an automatic device makes these parts not live, when the enclosure is opened or removed	<i>Only with the aid of tool</i>		P
16 f	Live parts are inaccessible to the test rod through openings for adjustment of pre-set controls	<i>Not applicable.</i>		N

17	SEPARATION				
17 a	Separation method of the applied part from live parts so that allowable leakage currents are not exceeded	<i>No applied part</i>			
17 a 1	Basic insulation - applied part earthed				N
17 a 2	By protectively earthed conductive part (e.g. screen)				N
17 a 3	By separate earthed intermediate circuit				N
17 a 4	By double or reinforced insulation				N
17 a 5	By protective impedances limiting current to applied part	.			N
17 a 6	Other method, e.g. specified in particular standard				N
	Equipment:				
	Initials Tester / Date:				
	Additional leakage current test in single fault conditions				
Fault condition (description)	Earth leakage current	Enclosure leakage current	Patient leakage current	Patient auxiliary current	
17 c	There is no conductive connection between applied parts and accessible conductive parts, which are not protectively earthed				P
17 d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I equipment)	<i>Not used</i>			N
	Adequate isolation of accessible metal parts from motor shaft				N
	Rated motor voltage				N
	Test voltage				N
	Air clearances/creepage distances (mm)/(mm)				N
17 g	Separation method of accessible parts other than applied parts from live parts so that allowable leakage currents are not exceeded				
17 g 1	Basic insulation - accessible part earthed				P
17 g 2	By protectively earthed conductive part (e.g. screen)				P
17 g 3	By separate earthed intermediate circuit	<i>Not applicable.</i>			N
17 g 4	By double or reinforced insulation	<i>Transformer</i>			N

17 g 5	By protective impedances limiting current to accessible part		N
	Leakage currents measurements, when required		N
17 h	Adequate arrangements used to isolate defibrillation-proof applied parts from other parts		N
	Impulse voltage tests		N
	Peak voltage between Y1 and Y2 does not exceed 1 V		N
	After recovery time equipment continues to perform its intended function		N

18	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION		
18 a	Sufficiently low impedance to the protective earth terminal(18 f and 18 g)		P
18 b	Suitable connection between protective earth terminal and protective conductor in the installation (18 f)		P
18 e	Means for connection of potentially equalisation conductor complies with specified requirements	<i>Not used</i>	N
	This connection complies with following requirements:		N
	- readily accessible		N
	- no possibility to accidental disconnection in normal use		N
	- conductor is detachable without the use of a tool		N
	- power supply cord does not include potential equalisation conductor		N
	- connection is marked with symbol		N

18 f	Impedance of protective earthing system: Impedance between any accessible metal part and: 1) protective earth terminal (PE) (requirement: R max. 0.1 Ohm), 2) protective earth contact in appliance inlet (requirement: R max. 0.1 Ohm), 3) protective earth contact in the mains plug Test equipment: See attached list. (requirement: R max. 0,2 Ohm), are tabled below:	$U = 0,57V$ $I = 30A$ $T = 2min.$			P
	Equipment:	N1514, N2332, N1585			
	Initials Tester / Date:	JohnnyG / 11-2000			
Accessible part and its location		R (Ohm) measured against (numbers see above)			
		1 PE	2 inlet	3 plug	
Inlet- Ground			0,019		
18 g	If the impedance of protective earth connections other than in 18 f exceeds 0.1 Ohm, the allowable value of the enclosure leakage current is not exceeded in single fault condition	No			N
18 k	Functional earth terminals are not used to provide protective earthing				P
18 l	For Class II equipment with isolated internal screens and with a power supply cord:	Class I equipment			N
	- the third conductor is used only as functional earth of these screens and is coloured green/yellow				N
	- insulation of such screens and all internal wiring connected to them is double insulation or reinforced insulation (see also 20.3)				N
	- marking of functional earth terminal is distinguished from protective earth terminal and is explained in accompanying documents				N
	Test of insulation (see Clause 20)				N

19	CONTINUOUS LEAKAGE CURRENTS AND PATIENTS AUXILIARY CURRENTS				
19.1	General requirements (tests see 19.4)				
19.1 g	Equipment with multiple patient connections: Patient leakage current and patient auxiliary current do not exceed allowable values while one or more patient connections are disconnected from the patient or disconnected from the patient and earthed				N
19.2	Single fault conditions (tests see 19.4)				
19.3	Allowable values (see 19.4)				
19.4	Tests before humidity preconditioning treatment				
	Equipment:				N2239, N2718, N2266, N3171
	Initials Tester / Date:				JohnyG / 11-2000
Type of leakage current	In normal condition		In single fault condition		
	Allowed value (µA)	Measured max. value (µA)	Allowed value (µA)	Measured max. value (µA)	
Earth leakage current	500	184	1000	381	
Enclosure leakage current	100	<5	500	<5	
Patient leakage current (p.l.c.), a.c. :	B, BF: 100 CF: 10	—	B, BF: 500 CF: 50	—	
Patient leakage current (p.l.c.), d.c. :	B, BF: 10 CF: 10	—	B, BF: 50 CF: 50	—	
P.l.c. (110 % of the mains voltage on the signal input part or signal output part)	—	—	B: 5000 BF, CF: —	113	
P.l.c. (110 % of mains voltage on the applied part)	—	—	B: — BF: 5000 CF: 50	—	
Patient auxiliary current, a.c. :	B, BF: 100 CF: 10	—	B, BF: 500 CF: 50	—	
Patient auxiliary current, d.c. :	B, BF: 10 CF: 10	—	B, BF: 50 CF: 50	—	
Comments					
	The values listed are the maximum values.				

19.4	Tests after humidity preconditioning treatment	See comments below.			
	Equipment:	N2239, N2718, N2266, N3171			
	Initials Tester / Date:	JohnnyG / 11-2000			
Type of leakage current	In normal condition		In single fault condition		
	Allowed value (µA)	Measured max. value (µA)	Allowed value (µA)	Measured max. value (µA)	
Earth leakage current	500	185	1000	382	
Enclosure leakage current	100	<5	500	<5	
Patient leakage current (p.l.c.), a.c. :	B, BF: 100 CF: 10	—	B, BF: 500 CF: 50	—	
Patient leakage current (p.l.c.), d.c. :	B, BF: 10 CF: 10	—	B, BF: 50 CF: 50	—	
P.l.c. (110 % of the mains voltage on the signal input part or signal output part)	—	—	B: 5000 BF, CF: —	113	
P.l.c. (110 % of mains voltage on the applied part)	—	—	B: — BF: 5000 CF: 50	—	
Patient auxiliary current, a.c. :	B, BF: 100 CF: 10	—	B, BF: 500 CF: 50	—	
Patient auxiliary current, d.c. :	B, BF: 10 CF: 10	—	B, BF: 50 CF: 50	—	
Comments					
	The values listed are the maximum values.				

20	DIELECTRIC STRENGTH (at operating temperature)					
	Overall compliance with Clause 20					P
	Equipment:		High voltage supply : N1979			
	Initials Tester / Date:		JohnyG / 11-2000			
Equipment	Insulation under test	Insulation resistance *)	Reference voltage	Test voltage	Remarks, observations	
All equipment types	A-a ₁		250 V AC	1 500 V AC	OK	
	A-a ₂					
	A-b					
	A-c					
	A-e		250 V AC	4 000 V AC	OK	
	A-f		250 V AC	1 500 V AC	OK	
	A-g					
	A-j					
	A-k		250 V AC	4 000 V AC	OK	
Equipment types with applied part	B-a		250 V AC	4 000 V AC	OK	
	B-b					
	B-c					
	B-d					
	B-e					
*) IEC 601-1 does not require to measure this						

20	DIELECTRIC STRENGTH (after humidity preconditioning treatment)					
	Overall compliance with Clause 20					P
	Equipment:		Humidity room : N3205 High voltage supply : N601			
	Initials Tester / Date:		JohnyG / 11-2000			
Equipment	Insulation under test	Insulation resistance *)	Reference voltage	Test voltage	Remarks, observations	
All equipment types	A-a ₁		250 V AC	1 500 V AC	OK	
	A-a ₂					
	A-b					
	A-c					
	A-e		250 V AC	4 000 V AC	OK	
	A-f		250 V AC	1 500 V AC	OK	
	A-g					
	A-j					
	A-k		250 V AC	4 000 V AC	OK	
Equipment types with applied part	B-a		250 V AC	4 000 V AC	OK	
	B-b					
	B-c					
	B-d					
	B-e					

*) IEC 601-1 does not require to measure this

21	MECHANICAL STRENGTH		
21 a	Rigidity of enclosure (45 N test force)	Tested with 45 N. No damage to enclosure parts.	P
21 b	Strength of enclosure part and any component thereon (Impact hammer test, 0.5 J).	No damage resulting in a safety hazard.	P
21 c	On portable equipment carrying handles or grips withstand the requirements of the loading test. (Test force four times the weight of equipment)	No handles or grips used	N

21.3	No damage to parts of patient support and/or immobilisation system after the loading test (1350 N and 2700 N tests)	<i>No patient support parts used</i>	N
	The test force for foot rests and chairs shall be twice the specified maximum load or, if not specified, the test force shall be 2,7 kN. The test force shall be distributed over an area of 0,1 m ² surface for 1 minute.		N
21.5	Hand-held equipment or equipment parts are safe after drop test (dropping height 1 m)	<i>Not hand-held equipment</i>	N
21.6 a	Portable and mobile equipment is able to withstand rough handling.		P
21.6 b	Propel test of mobile equipment (performed 20 times). Equipment complies with requirements of this standard.	<i>Not applicable.</i>	N

22	MOVING PARTS		
22.2 a	Moving parts of transportable equipment are provided with guards which form an integral part of the equipment	<i>No moving parts used</i>	N
22.2 b	Moving parts of stationary equipment are provided with similar guards as above unless it is evident that equivalent protection is separately provided during installation		N
22.3	Cords (ropes), chains and bands are confined so they cannot run off or jump out of their guiding devices		N
	Other means used to prevent a safety hazard		N
	Mechanical safeguard means are removable only with a tool		N
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation of the control		N
22.6	Parts of equipment subject to mechanical wear are accessible for inspection		N

22.7	To remove an unexpected safety hazard caused by an electrically produced mechanical movement, there are means for emergency switching of a relevant part		N
	The means for emergency switching are readily identifiable and accessible and do not introduce a further safety hazard		N
	Current breaking capability		N
	Means for stopping of movements operate as a result of one single action		N

23	SURFACES, CORNERS AND EDGES		
	There are no rough surfaces, sharp corners, flange or frame edges and burrs which may cause injury or damage	<i>The edges are well rounded.</i>	P

24	STABILITY IN NORMAL USE		
24.1	Equipment does not overbalance, when tilted through an angle of 10°	<i>Tested.</i>	P
24.3	If equipment overbalances when tilted 10°, it does not overbalance when tilted:	<i>See above</i>	N
	- 5° in any position of normal use, excluding transport		N
	- 10° in the condition specified for transport		N
	The equipment carries a warning notice for transport		N
24.6 a	Equipment or its parts with a mass of more than 20 kg:		N
	- is provided with handling devices (grips etc.)		N
	- is provided with handling instructions for lifting and assembling		N
4.6 b	Portable equipment with a mass of more than 20 kg carrying handle(s) suitably placed that equipment may be carried by 2 or more persons		N

25	EXPELLED PARTS		
25.1	Protective means are provided where expelled parts of the equipment could constitute a safety hazard	<i>Not applicable.</i>	N

25.2	Display vacuum tubes with a face dimension of 16 cm or larger are intrinsically safe with respect to effects of implosion of tubes and to mechanical impact, or the enclosure of the equipment is provided with adequate protection against implosion	<i>Not applicable.</i>	N
	Certificate of the test provided		N

26	VIBRATION AND NOISE		
		<i>No general requirement.</i>	

27	PNEUMATIC AND HYDRAULIC POWER		
		<i>No general requirement.</i>	

28	SUSPENDED MASSES		
28.3	Suspension systems with safety devices:	<i>No suspended masses</i>	N
	Suspension systems include a safety device with adequate safety factors to protect user or patient from hazards		N
	If after activation of a safety device the equipment can still be used, the activation of the device, e.g. a secondary rope, becomes obvious to the operator		N
28.4	Suspension systems of metal without safety devices:		N
	The construction of the suspension complies with:		N
28.4 1	The TOTAL LOAD does not exceed the SAFE WORKING LOAD		N
28.4 2	Where it is unlikely that supporting characteristics will be impaired by wear, corrosion, material fatigue or ageing, the SAFETY FACTOR of all supporting parts is not less than 4		N
28.4 3	Where impairment by wear, corrosion, material fatigue is expected, the SAFETY FACTOR is not less than 8		N
28.4 4	Where metal having a specific elongation at break of less than 5% is used in supporting components, the SAFETY FACTOR is not less than 1.5 times those given in 2) and 3) above		N

28.4 5	Sheaves, sprockets, band wheels and guides are so designed that the SAFETY FACTORS of this Sub-clause shall be maintained for a specified minimum life till replacement of the ropes, chains and bands		N
28.5	Dynamic loads:	No general requirement.	

29	X-RADIATION		
29.1	Diagnostic X-ray equipment, see IEC 601-1-3. Radiotherapy equipment, see relevant Particular standard	No X-radiation	N
29.2	For equipment not intended to produce X-radiation for diagnostic and therapeutic purposes, ionising radiation emitted by vacuum tubes excited by voltages exceeding 5 kV does not produce an exposure exceeding 130 nC/kg (0.5 mR)		N

30	ALPHA, BETA, GAMMA, NEUTRON RADIATION AND OTHER PARTICLE RADIATION		
		No general requirement.	

31	MICROWAVE RADIATION		
		No general requirement.	

32	LIGHT RADIATION (INCLUDING LASERS)		
		No general requirement.	

33	INFRA-RED RADIATION		
		No general requirement.	

34	ULTRAVIOLET RADIATION		
		No general requirement.	

35	ACOUSTICAL ENERGY (INCLUDING ULTRA-SONICS)		
		No general requirement.	

36	ELECTROMAGNETIC COMPATIBILITY			
	IEC 60601-1-2 (1993)	<i>Compliance documented by the manufacturer.</i>		P

37 - 41	REQUIREMENTS FOR CATEGORY AP AND APG EQUIPMENT			
	See additional test report form.	<i>Not applicable.</i>		N

42	EXCESSIVE TEMPERATURES						
	Ambient temperature during measurements:	See tables below.					
	Humidity:	40%rh					
	Atmospheric pressure:	995hPa					
	Equipment:	Humidity : N2531 Pressure : N2842					
	Initials Tester / Date:	JohnnyG / 11-2000					
42.1 - 42.2	Determination of the temperature with thermocouples:						P
	Equipment:	N3008, N3635, N2859, N3132					
	Initials Tester / Date:	JohnnyG / 11-2000					
Quantity		Rated	Used in tests		Remarks		
Supply voltage, V		100-250V AC	90, 275 V AC				
Supply power, VA		—	—				
Output power, VA		—	—				
Measuring point		Measured temp. Δt (°K)	Calculated temp. T (°C)	Measured temp. Δt (°K)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks
A: IP 90Vac, 60Hz B: IP 275Vac, 60Hz		A		B			
1. Ambient, T = 25° C		—	—	—	—	—	
2. T1 coil		40	80	43	68	Cl.B 130°C	Table Xa
3. T1 core		36	76	39	64	""	Table Xa
4. L1 coil		35	60	30	55		Table Xb
5. BT1 body		26	51	26	51		Table Xb
6. V1 body		30	55	31	56		Table Xb
7. L6 coil		29	54	29	54		Table Xb
8. T1 coil for inverter		65	105	65	105	Cl.B 130°C	Table Xa
9. T1 core for inverter		70	110	70	110	""	Table Xa
10. F1 coil for inverter		58	83	58	83		Table Xb
11. Surface of PC		13	53	13	53	75	Table Xa
12. SMP for building-in: Skynet SNP-8086-M. See Nemko ref. 200039133							
Comments	According to IEC 601-1 clause 42.1, table Xa and Xb, 40 ⁰ C or 25 ⁰ C is added to the temperature rise for determination of the final temperature T.						
	Model PPC-150M-zT						

Measuring point	Measured temp. Δt (°K)	Calculated temp. T (°C)	Measured temp. Δt (°K)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks	
A: IP 90Vac, 60Hz B: IP 275Vac, 60Hz	A		B				
1. Ambient, $T = 25^{\circ}\text{C}$	—	—	—	—	—		
2. L1 coil	60	85	50	75		Table Xb	
3. BD1 body	69	94	57	83		Table Xb	
4. C8 body	46	71	42	67		Table Xb	
5. T1 coil	70	110	76	116	Cl.B	Table Xa	
6. T1 core	67	107	73	113	« «	Table Xa	
7. L4 coil	76	101	79	104		Table Xb	
8. L3 coil	61	86	63	88		Table Xb	
9. HS body of Q1	41	66	42	67		Table Xb	
10. V36 body	29	54	29	54		Table Xb	
11.cpu body	37	62	36	61		Table Xb	
12.H.DD body	25	50	25	50		Table Xb	
13. F.DD body	19	44	19	44		Table Xb	
14. CD rom body	27	52	27	52		Table Xb	
15. V1 body	29	54	29	54		Table Xb	
16. L48 body	26	51	26	51		Table Xb	
17. T1 coil for inverter	62	102	62	102	Cl.B	Table Xa	
18. T1 core for inverter	48	88	48	88	“”	Table Xa	
19. L1 coil for inverter	56	81	56	81		Table Xb	
20. Surface of PC	13	53	13	53	75	Table Xa	
12. SMP for building-in: Skynet SNP-8086-M. See Nemko ref. 200039133							
Comments	According to IEC 601-1 clause 42.1, table Xa and Xb, 40 ⁰ C or 25 ⁰ C is added to the temperature rise for determination of the final temperature T.						
	Model PPC-120M-zT						

Measuring point	Measured temp. Δt (°K)	Calculated temp. T (°C)	Measured temp. Δt (°K)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks	
A: IP 90Vac, 60Hz B: IP 275Vac, 60Hz	A		B				
1. Ambient, $T = 25^{\circ}\text{C}$	—	—	—	—	—		
2. L1 coil	52	77	43	68		Table Xb	
3. BD1 body	65	90	50	75		Table Xb	
4. C8 body	40	65	34	59		Table Xb	
5. T1 coil	70	110	71	111	Cl.B	Table Xa	
6. T1 core	62	102	66	106	Cl.B	Table Xa	
7. L4 coil	70	95	71	96		Table Xb	
8. L3 coil	56	81	56	81		Table Xb	
9. HS body of Q1	37	62	37	62		Table Xb	
10. BT1 body	19	44	18	43		Table Xb	
11. V2 body	22	47	20	45		Table Xb	
12. upc body	24	49	22	47		Table Xb	
13. H.DD body	17	42	14	39		Table Xb	
14. F.DD body	13	38	11	36		Table Xb	
15. CD rom body	17	42	15	40		Table Xb	
16. V3 body	25	50	24	49		Table Xb	
17. T2 coil for inverter	57	97	57	97	Cl.B	Table Xa	
18. T2 core for inverter	54	94	55	95	Cl.B	Table Xa	
19. F3 coil for inverter	50	75	49	74		Table Xb	
20. Surface of PC	10	50	8	48	75	Table Xa	
12. SMP for building-in: Skynet SNP-8086-M. See Nemko ref. 200039133							
Comments	According to IEC 601-1 clause 42.1, table Xa and Xb, 40°C or 25°C is added to the temperature rise for determination of the final temperature T.						
	Model PPC-153M-zT						

42.1 - 42.2	Determination of the temperature with thermocouples:	Block vent test			P
Measuring point	Measured temp. Δt (°K)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks	
Power input 250Vac, 60Hz					
<i>Ambient, T = 25° C</i>	—	—	—		
<i>1. L1 coil</i>	<i>60</i>	<i>85</i>		<i>Table Xb</i>	
<i>2. BD1 body</i>	<i>67</i>	<i>92</i>		<i>Table Xb</i>	
<i>3. C8 body</i>	<i>54</i>	<i>79</i>		<i>Table Xb</i>	
<i>4. T1 coil</i>	<i>86</i>	<i>126</i>	<i>Cl.B</i>	<i>Table Xa</i>	
<i>5. T1 core</i>	<i>82</i>	<i>122</i>	<i>40°</i>	<i>Table Xa</i>	
<i>6. L4 coil</i>	<i>87</i>	<i>112</i>		<i>Table Xb</i>	
<i>7. L3 coil</i>	<i>72</i>	<i>97</i>		<i>Table Xb</i>	
<i>8. H.S body & Q1</i>	<i>53</i>	<i>87</i>		<i>Table Xb</i>	
<i>9. V36 body</i>	<i>46</i>	<i>71</i>		<i>Table Xb</i>	
<i>10.cpu body</i>	<i>55</i>	<i>80</i>		<i>Table Xb</i>	
<i>11. H.DD body</i>	<i>34</i>	<i>59</i>		<i>Table Xb</i>	
<i>12.F.DD body</i>	<i>24</i>	<i>49</i>		<i>Table Xb</i>	
<i>13.CD rom body</i>	<i>38</i>	<i>63</i>		<i>Table Xb</i>	
<i>14.V1 body</i>	<i>43</i>	<i>68</i>		<i>Table Xb</i>	
<i>15.L48 body</i>	<i>44</i>	<i>69</i>		<i>Table Xb</i>	
<i>16.T1 coil for inverter</i>	<i>68</i>	<i>108</i>	<i>Cl.B</i>	<i>Table Xa</i>	
<i>17.T1 core for inverter</i>	<i>55</i>	<i>95</i>	<i>40°</i>	<i>Table Xa</i>	
<i>18.L1 coil for inverter</i>	<i>53</i>	<i>78</i>		<i>Table Xb</i>	
<i>19. Surface of enclosure</i>	<i>21</i>	<i>61</i>	<i>75</i>	<i>Table Xa</i>	
Comments	According to IEC 601-1 clause 42.1, table Xa and Xb, 40 ⁰ C or 25 ⁰ C is added to the temperature rise for determination of the final temperature T.				
	<i>Model PPC-120M</i>				

Measuring point	Measured temp. Δt (°K)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks Block vent test	
Power input 250Vac, 60Hz					
<i>Ambient, T = 25° C</i>	—	—	—		
1. L1 coil	60	85		Table Xb	
2. BD1 body	67	92		Table Xb	
3. C8 body	51	76		Table Xb	
4. T1 coil	90	130	Cl.B	Table Xa	
5. T1 core	83	123	40°	Table Xa	
6. L4 coil	88	113		Table Xb	
7. L3 coil	74	99		Table Xb	
8. H.S body & Q1	55	80		Table Xb	
9. BT1 body	39	64		Table Xb	
10. V2 body	40	65		Table Xb	
11. CPU body	43	68		Table Xb	
12. HDD body	31	56		Table Xb	
13. FDD body	23	48		Table Xb	
14. CD rom body	29	54		Table Xb	
15. U3 body	40	65		Table Xb	
16. T2 coil for inverter	63	103	Cl.B	Table Xa	
17. T2 core for inverter	60	100	40°	Table Xa	
18. F3 coil for inverter	58	83		Table Xb	
19. Surface of enclosure	25	65	75	Table Xb	
Comments	According to IEC 601-1 clause 42.1, table Xa and Xb, 40° C or 25° C is added to the temperature rise for determination of the final temperature T.				
	Model PPC-153M				

Measuring point	Measured temp. Δt (°K)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks Block vent test	
Power input 250Vac, 60Hz					
<i>Ambient, T = 25° C</i>	—	—	—		
1. T1 coil	65	105	Cl.B	Table Xa	
2. T1 core	62	102	Cl.B	Table Xa	
3. L1 coil	51	76		Table Xb	
4. BT1 body	51	76		Table Xb	
5. U1 body	58	83		Table Xb	
6. L6 coil	56	81		Table Xb	
7. T1 coil for inverter	70	110	Cl.B	Table Xa	
8. T1 core for inverter	77	117	Cl.B	Table Xa	
9. F1 coil for inverter	68	93		Table Xb	
10. Surface of PC	34	73	75	Table Xa	
Comments	According to IEC 601-1 clause 42.1, table Xa and Xb, 40 ⁰ C or 25 ⁰ C is added to the temperature rise for determination of the final temperature T.				
	Model PPC-150M				

42.1 - 42.2	Determination of the temperature with thermocouples:	Installed fan test			P
Measuring point	Measured temp. Δt (°K)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks	
Power input 250Vac, 60Hz					
<i>Ambient, T = 24° C</i>	—	—	—		
<i>1. L1 coil</i>	<i>50</i>	<i>75</i>		<i>Table Xb</i>	
<i>2. BD1 body</i>	<i>57</i>	<i>82</i>		<i>Table Xb</i>	
<i>3. C8 body</i>	<i>45</i>	<i>70</i>		<i>Table Xb</i>	
<i>4. T1 coil</i>	<i>78</i>	<i>118</i>	<i>Cl.B</i>	<i>Table Xa</i>	
<i>5. T1 core</i>	<i>74</i>	<i>114</i>	<i>40°</i>	<i>Table Xa</i>	
<i>6. L4 coil</i>	<i>81</i>	<i>106</i>		<i>Table Xb</i>	
<i>7. L3 coil</i>	<i>66</i>	<i>91</i>		<i>Table Xb</i>	
<i>8. H.S body & Q1</i>	<i>44</i>	<i>69</i>		<i>Table Xb</i>	
<i>9. V36 body</i>	<i>40</i>	<i>65</i>		<i>Table Xb</i>	
<i>10.cpu body</i>	<i>73</i>	<i>98</i>		<i>Table Xb</i>	
<i>11. H.DD body</i>	<i>32</i>	<i>57</i>		<i>Table Xb</i>	
<i>12.F.DD body</i>	<i>18</i>	<i>43</i>		<i>Table Xb</i>	
<i>13.CD rom body</i>	<i>28</i>	<i>53</i>		<i>Table Xb</i>	
<i>14.V1 body</i>	<i>42</i>	<i>67</i>		<i>Table Xb</i>	
<i>15.L48 body</i>	<i>54</i>	<i>79</i>		<i>Table Xb</i>	
<i>16.T1 coil for inverter</i>	<i>61</i>	<i>101</i>	<i>Cl.B</i>	<i>Table Xa</i>	
<i>17.T1 core for inverter</i>	<i>47</i>	<i>87</i>	<i>40°</i>	<i>Table Xa</i>	
<i>18.L1 coil for inverter</i>	<i>57</i>	<i>82</i>		<i>Table Xb</i>	
<i>19. Surface of enclosure</i>	<i>34</i>	<i>74</i>	<i>75</i>	<i>Table Xa</i>	
Comments	According to IEC 601-1 clause 42.1, table Xa and Xb, 40 ⁰ C or 25 ⁰ C is added to the temperature rise for determination of the final temperature T.				
	<i>Model PPC-120M</i>				

Measuring point	Measured temp. Δt (°K)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks Installed fan test	
Power input 250Vac, 60Hz					
Ambient, T = 25° C	—	—	—		
1. L1 coil	49	74		Table Xb	
2. BD1 body	56	81		Table Xb	
3. C8 body	42	67		Table Xb	
4. T1 coil	78	118	Cl.B	Table Xa	
5. T1 core	73	113	40°	Table Xa	
6. L4 coil	81	106		Table Xb	
7. L3 coil	66	91		Table Xb	
8. H.S body & Q1	47	72		Table Xb	
9. BT1 body	39	64		Table Xb	
10. U2 body	68	93		Table Xb	
11. CPU body	72	97		Table Xb	
12. HDD body	23	48		Table Xb	
13. FDD body	13	38		Table Xb	
14. CD rom body	20	45		Table Xb	
15. U3 body	38	63		Table Xb	
16. T2 coil for inverter	55	95	Cl.B	Table Xa	
17. T2 core for inverter	52	92	40°	Table Xa	
18. F3 coil for inverter	50	75		Table Xb	
19. Surface of enclosure	31	71	75	Table Xb	
Comments	According to IEC 601-1 clause 42.1, table Xa and Xb, 40° C or 25° C is added to the temperature rise for determination of the final temperature T.				
	Model PPC-153M				

42.1 - 42.2	Determination of the temperature rise of copper windings by the resistance method: $\Delta t = \frac{R_2 - R_1}{R_1} (234.5 + t_1) - (t_2 - t_1)$			Not applicable. SMP used				N
	Equipment:							
	Initials Tester / Date:			/				
Quantity		Rated		Used in tests		Remarks		
Supply voltage, V								
Supply power, VA		—		—				
Output power, VA		—		—				
Winding	R ₁ (Ω)	R ₂ (Ω)	Room temperat.		Final temperat.		Allowed T (°C)	Remarks
			t ₁ (°C)	t ₂ (°C)	Δt (°K)	T (°C)		
Comments	According to IEC 60601-1 clause 42.1, table Xa and Xb, 40 ⁰ C or 25 ⁰ C is added to the temperature rise for determination of the final temperature T.							
42.3	Surface temperatures of applied parts not intended to supply heat to a patient do not exceed 41°C			No applied parts used				N
42.5	Guards for preventing contact with hot accessible surfaces are removable only with the aid of a tool			Not applicable. No hot accessible surfces				N

43	FIRE PREVENTION		
43.1	Strength and rigidity of the equipment are sufficient to avoid fire hazards (see 21)	<i>The equipment is well constructed with regard to avoid fire hazard.</i>	P
43.2	Oxygen enriched atmospheres:	<i>No general requirement.</i>	

44	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION, DISINFECTION AND COMPATIBILITY		
44.2	Overflow		
	Equipment containing a liquid reservoir:	<i>No containing a liquid reservoir used</i>	N
	- The equipment is electrically safe after 15% overfill steadily over a period of 1 min		N
	- Transportable equipment is electrically safe after additionally having been tilted through 15° in least favourable direction(s) (if necessary with refilling)		N
	No signs of wetting of uninsulated live parts		N
	Dielectric strength test (if deemed necessary)		N
44.3	Spillage		
	Safety of the equipment does not change in consequence of spillage test performed by the method mentioned in the standard (200 ml of water for approximately 15 s from a height of max. 5 cm)	<i>Not applicable.</i>	N
44.4	Leakage		
	Safety of the equipment does not change in consequence of leakage test performed by the method mentioned in the standard (drops of water). Equipment shall be so constructed that liquid which might escape in a single fault condition does not cause a safety hazard(see also Sub-clause *52.4.1)	<i>Not applicable.</i>	N
44.5	Humidity		
	Checked by the pre-conditioning treatment and tests (see 4.10)	<i>48H</i>	P
44.6	Ingress of liquids		
	Equipment checked by relevant tests of IEC 60 529	<i>Not applicable. IPX0</i>	N
	Equipment withstands dielectric strength test in Clause 20.		N
	Water, if entered equipment, has no harmful effect, in particular there is no trace of water on insulation for which creepage distances are specified		N

44.7	Cleaning, sterilisation and disinfection		
	Equipment/equipment parts capable of withstanding cleaning, sterilisation or disinfection likely to be encountered in normal use or specified by the manufacturer	<i>See Sub-clause 6.8.2 d.</i>	P
	Test with saturated steam at 134 degrees C+/-4 for 20 cycles, each of 20 min duration	<i>Not applicable.</i>	N
	Method specified by the manufacturer in instructions for use	<i>See Sub-clause 6.8.2 d.</i>	P
	Safety of the equipment not impaired by the test. No appreciable signs of deterioration. Dielectric strength test specified in Clause 20. withstood.	<i>Not applicable.</i>	N
44.8	Compatibility with substances used with the equipment:	<i>No general requirement</i>	

45	PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE		
45.2	Pressure vessel with a pressure volume greater than 200 kPa x l, and pressure greater than 50 kPa, withstands the hydraulic test pressure.	<i>No pressure vessels used</i>	N
	Hydraulic test pressure: (The test pressure shall be maximum permissible working pressure multiplied by a factor obtained from Fig. 38).		N
45.3	The maximum pressure to which a part can be subjected in normal condition and single fault condition does not exceed the maximum permissible working pressure for the part		N
	The used maximum pressure is the highest of the following:		N
45.3 a	Rated maximum supply pressure from an external source		N
45.3 b	Pressure setting of a pressure relief device provided as part of the assembly		N
45.3 c	Maximum pressure that can be developed by an air compressor that is part of the assembly, unless the pressure is limited by a pressure-relief device		N
45.7	Equipment incorporates pressure-relief device(s) where excessive pressure could occur		N
	If yes, it complies with all the following requirements:		N
45.7 a	Connected as close as possible to the pressure vessel or parts of system it is intended to protect		N

45.7 b	Readily accessible for inspection, maintenance and repair		N
45.7 c	Not capable of being adjusted or rendered inoperative without a tool		N
45.7 d	Its discharge opening located and directed so, that released materials is not directed towards any person		N
45.7 e	Operation of device does not deposit material on parts causing possible safety hazard		N
45.7 f	Ensures that the pressure does not exceed the maximum permissible working pressure by more than 10%, if a failure occurs in the control of the supply pressure		N
45.7 g	No shut-off valve between the pressure-relief device and the parts it is intended to protect		N
45.7 h	Minimum number of cycles of operation is 100 000, except for bursting disks		N

46	HUMAN ERRORS		
		<i>No general requirement.</i>	

47	ELECTROSTATIC DISCHARGES		
		<i>No general requirement.</i>	

48	BIOCOMPATIBILITY		
	Equipment parts and accessories intended to come into contact with biological tissues, cells or body fluids assessed and documented as given in ISO 10993-1. Inspection of information provided by manufacturer.	<i>No parts of the equipment or accessories are intended to come into contact with biological tissues, cells or body fluids.</i>	N

49	INTERRUPTION OF POWER SUPPLY		
49.1	If automatically resetting thermal cut-outs and overcurrent releases are used, they give a safe condition by such resetting	<i>Not applicable.</i>	N
49.2	Interruption and restoration of the power supply do not result in hazards		P
49.3	Means are provided for removal of mechanical constraints on patients in case of a supply mains failure	<i>Not applicable.</i>	N

50	MARKING OF CONTROLS AND INSTRUMENTS		
50.1		<i>See Sub-clause 6.3.</i>	

51	PROTECTION AGAINST HAZARDOUS OUTPUT		
51.1	Intentional exceeding of safety limits.	<i>No general requirement (cf. Appendix A, Sub-clause A2)</i>	
51.2	Indication of parameters relevant to safety.	<i>No general requirement (cf. Appendix A, Sub-clause A2)</i>	
51.3	Reliability of components.	<i>See Sub-clause 3.6 f.</i>	
51.4	Equipment providing both low- and high-intensity outputs. Minimised possibility of high intensity output being selected accidentally	<i>Not applicable.</i>	N
51.5	Incorrect output.	<i>No general requirement</i>	

52	ABNORMAL OPERATION AND FAULT CONDITIONS		
52.1	Equipment shall be so designed and manufactured that even in single fault condition no safety hazard as described under Sub-clause 52.4 exists (see 3.1 and 13)		P
52.1	Safety of equipment incorporating programmable electronic systems (PES) conforms to the rules of future IEC 601-1-4	<i>The equipment does not include programmable electronic subsystems as specified in IEC 60601-1-4, 1996</i>	
52.5.1	Overloading of mains supply transformers	<i>Tests see Sub-clause 57.9. See Nemko ref.: 200039133</i>	P
52.5.2	Failure of thermostats	<i>Not used</i>	N
52.5.3	Short-circuiting one part of a double insulation	<i>Not applicable.</i>	N
52.5.4	Interruption of the protective earth conductor (tests as described in Sub-clause 19.4)		P
52.5.5	Impairment of cooling. Temperatures do not exceed 1.7 times values of Clause 42, Tables Xa and Xb, minus 17.5 degrees C.	<i>Fan used</i>	P
52.5.6	Locking of moving parts (see also 52.5.8)	<i>No moving parts</i>	N

52.5.7	Interruption and short-circuiting of motor capacitors (see also 52.5.8)	<i>Not applicable. Not used</i>							N
	Equipment:								
	Initials Tester / Date:	/							
Capacitor and winding	Short circuit	Open circuit	R ₁ (Ω)	R ₂ (Ω)	t ₁ (°C)	t ₂ (°C)	Δt (°K)	Final t (°C)	
Comments									
52.5.8	Additional tests for motor operated equipment:	<i>Not used</i>							N
52.5.9	Failure of components (refer to Table in Clause 56)	<i>See the table below</i>							P
	X1 and X2 capacitors between parts of opposite polarity in the mains part and complying with IEC 60 384-14 exempted from this requirement								
52.5.10	Overload								
52.5.10 a	Equipment with heating elements:	<i>Not used</i>							N
52.5.10 a 1	Thermostatically controlled equipment (see 52.5.10.c and d)								N
52.5.10 a 2	Equipment with heating elements with short-time rating (see 52.5.10 c and e)								N
52.5.10 a 3	Other equipment with heating elements (see 52.5.10 c)								N
52.5.10 b	Equipment having motors, which are a part of equipment (see 52.5.5 - 52.5.8 and 52.5.10 f - 52.5.10 h)								N
52.5.10 b 1	Mention circuit/component concerned (e.g. regulator, capacitor, wiring, etc.) and mention the fault condition (e.g. disconnected, short-circuited, etc.). Mention creepage-distances separately if applicable (refer to the text of 52.5 above 52.5.1 in the 601-1 standard)								N
52.5.10 b 2	Mention for example safety hazards according to 3.1 and 13 and 52.4								N

Test No from 52.5	Applied single fault condition (refer to 52.5) 1)	Observed result (e.g. hazards which arise or not) 2)	
	<i>See Nemko ref. No. 200039133</i>		

53	ENVIRONMENTAL TESTS	
	<i>See Sub-clause 4.10 and Clause 10.</i>	

54	CONSTRUCTIONAL REQUIREMENTS - GENERAL	
	<i>See Clause 55 to 59.</i>	

55	ENCLOSURES AND COVERS	
	<i>See Clause 16, 21 and 24.</i>	

56	COMPONENTS AND GENERAL ASSEMBLY - LIST OF CRITICAL COMPONENT PARTS			
Code	Approved by	Manufacturer, Type number, Nominal ratings	Operating-ratings	Location
Mains cord	<HAR>	R&L, WS-010, H03W-F 3G 0.75mm ²	250Vac, 16A	
Enclosure	UL		HB or better, min. 2.0 mm thick	
PCB	UL		94-1 or better	
CD-rom (Optional)	TUV, CSA, UL	XM-7004Bxx XM-1902Bxx X=0-9	5Vdc, 0.9A	
Appliance inlet	VDE	Supercom, SC-9 Inalways, 0711 Rong Feng, SS-130 Rong Feng, SS-7B	10A, 250Vac	
Mains fuse	UL, CSA	Conquer, GBP System General, PDC60240.A0 Conquer, GFP	12A 250Vac I/P 24Vdc/5.0A O/P 7A, 250Vac	
Mains switch	VDE, CSA	Fima, 1852	5A, 250Vac	
Lithium Battery	UL	SGS-Thomson, M4T28-BR12SH1	5V, 50mAh	
Ply switch for Keyboard mouse	UL, TUV	Raychem, SMD150-2018	1.10A, 5V	
DC fan for CPU	VDE, CSA, UL	Delta, AFB0512MA	12Vdc, 0.15A 8.47CFM	
Inverter transformers	Accept tested in equipment	Sen Huei, TRN-0067 and TRN-0064 TDK, SRW15/20EM-T11H004 NIA15/20EM-T11H004	Cl.B	
Mains transformer	See Nemko ref. No. 200039133	Adaptor: Skynet SNP-8086-M		
DC fan for DC power supplies	UL, TUV	Adda, AD0412MB-G70	12Vdc, 0.08A, 4.2CGM	
LCD module for model PPC-xxM-zT	Accept tested in equipment	Samsung, LT150Z-051	TFT type, 6V max. for input, 11.2mA, 690V for lamp.	
Alt.		Toshiba, LTM15C151A	TFT type, 5V max for input, 6mA, 710V for lamp.	
Inverter for Lc	Accept tested in equipment	Laruel Carry&Leap, TAD282	12V, 1.14A	

56.1	General	<i>Marking of components (refer to Table in Clause 56).</i>	
56.1 b	Component markings are according with conditions of use	<i>The components are used according to their ratings. All components in the mains part and applied part are marked or otherwise identified regarding their ratings.</i>	P
56.1 d	Fixing of components.	<i>The movement of components is prevented.</i>	P
56.1 f	Fixing of wiring.	<i>Conductors and connectors are adequately secured and insulated. Accidental detachment does not result in a safety hazard.</i>	P
56.3	Connections - general		
56.3 a	Incorrect interconnection of accessible connectors is prevented where a hazard may be caused	<i>No such interconnection</i>	N
	Accessible parts are separated from live parts (see 17 g)		P
	Plugs for connection of patient circuit cannot be connected to other outlets	<i>Not applicable. No such connection of patient</i>	N
	Medical gas connections are not interchangeable (see Sub-clause 6.6 and ISO R407)	<i>Not used</i>	N
56.3 b	Accessible conductive parts are prevented from becoming live when connection between different part of the equipment is broken		P
56.3 c	Connectors having conductive connection to patient are constructed so that no conductive connection of the connector remote from patient can contact earth or hazardous voltages	<i>Not applicable.</i>	N
	Test with flat conductive surface		N
	Test with straight unjointed test finger		N
	Test if able to be plugged into a mains socket		N
56.4	Connections of capacitors		
	Capacitors not connected between live parts and non- protectively earthed accessible conductive parts	<i>Not applicable.</i>	N
	Capacitors between the mains part and earthed accessible parts, comply with IEC 60384-14 or equivalent		P
	The enclosure of capacitors are not secured directly to non-protectively earthed accessible metal parts		P
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs		P

56.5	Protective devices		
	Protective devices which operate by producing a short circuit which results in operation of an overcurrent protection device in supply mains system not used (see also 59.3)		P
56.6	Temperature and overload control devices		
56.6 a	Thermal cut-outs which require soldering to reset are not used	<i>Not used</i>	N
	Thermal safety devices are provided to prevent temperature limits being exceeded		N
	An independent non-self resetting thermal cut-out is provided where the failure of a thermostat may cause a hazard		N
	The operating temperature of the above thermal cut-out is between the upper limit of the first thermostat and the safe limit for the function		N
	There is an audible alarm where loss of function could present a safety hazard		N
	Test of thermal cut-outs and overcurrent releases		N
	Heated liquid containers are protected against dangerous overheating when container is empty		N
56.6 b	Means provided for varying the temperature setting of thermostats, the temperature setting is clearly indicated		N
	The operating temperature of thermal cut-outs is clearly indicated		N
56.7	Batteries		
56.7 a 1	Adequately ventilation		P
56.7 a 2	Accidental short-circuiting is prevented (Note! Lithium batteries)		P
56.7 b	Incorrect polarity of connection prevented (Note! Lithium batteries) 1) Establish whether there is a possibility of making an incorrect battery connection. 2) Where such a possibility exists, establishing the effect of an incorrect battery connection.	<i>Not applicable. A back up Lithium battery used. Not internally powered equipment</i>	N
	Type of battery is clearly marked (see also 6.2 d)	<i>Battery type: M4T28-BR12SH1</i>	P
56.7 c	Battery state.	<i>No general requirement.</i>	N

56.8	Indicators			
	Unless indication is otherwise apparent to the operator from normal operating position , indicator lights are provided:		Colours, see Sub-clause 6.7.	P
	- to indicate that equipment is energised		See Sub-clause 6.3 a.	P
	- to indicate the operation of non-luminous heaters		Not applicable.	N
	- to indicate when output exists if a safety hazard could result		Not applicable. .	N
	Charging mode is visibly indicated to the operator		Not applicable.	N
56.10	Actuating parts of controls			
56.10 a	Accessible parts of electrical controls comply with requirements in Sub-clause 16 c		No actuating parts	N
56.10 b	Fixing, prevention of maladjustments:			N
	Actuating parts are adequately secured to prevent them working loose during normal use			N
	Controls are secured to prevent movement relative to scale marking			N
	Detachable indicating devices are prevented from incorrect connection without the use of a tool			N
	Equipment:			
	Initials Tester / Date:		/	
Rotating controls		Gripping diameter of the knob (mm)	Test torque (Nm)	Remarks
Pull controls		Axial pull, test force (Nm)		Remarks
56.10 c	Stops of adequate mechanical strength are provided on rotating or movable parts of controls, where necessary to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter where this could produce a safety hazard		Not applicable.	
	Manual torque test			
	Axial pull test			

56.11	Cord connected hand-held and foot-operated control devices		
56.11 a	Voltages on cord connected control devices do not exceed 25 V a.c. or 60 V d.c. or peak value		P
	Circuits isolated from mains part (see 17 g)		P
56.11 b	Hand-held control devices: No safety hazard as a result of the free fall test (Sub-clause 21.5)	<i>Not hand-held equipment</i>	N
	Foot-operated control devices able to support the weight of an adult human being. Test with an actuating force of 1350 N over an area of 625 mm ² . No damage to the device resulting in a safety hazard.		N
56.11 c	Hand-held and foot-operated control devices do not change their control setting when inadvertently placed in abnormal position		N
56.11 d	IP-classification of foot-operated control device at least IPX1		N
	Electrical switching parts specified for use in operating rooms at least IPX8		N
56.11 e	Provided with adequate means of anchoring as for power supply cords (see test of 57.4).		N

57	MAINS PARTS, COMPONENTS AND LAY-OUT		
57.1	Isolation from supply mains		
57.1 a	Means of isolation:		P
	The equipment has means for simultaneous disconnection of all supply poles		P
	Means for disconnection incorporated in equipment		P
	External means for disconnection are specified in accompanying documents	<i>Not applicable.</i>	N
57.1 d	Switches for mains disconnection comply with creepage distance and air clearances (IEC 60328 , replaced by IEC 60 61058-1)		P
57.1 f	Mains switches are not incorporated in power supply cord or flexible leads		P
57.1 g	The directions of movement of actuators of mains switches comply with IEC 60447	<i>Two-pole switch disconnects the voltage. Mounted according to IEC 60447.</i>	N
57.1 h	Suitable plug device used to isolate the non-permanently installed equipment from the supply mains		P
57.1 m	Fuses and semiconductor devices are not used as isolating devices		P

57.2	Mains connectors , appliance inlets and the like		
57.2 e	Auxiliary mains sockets outlets:	<i>Not used</i>	N
	- cannot accept a mains plug (does not apply to emergency trolleys)		N
	Number of socket-outlets on emergency trolleys are limited to maximum 4.		N
	- and they are properly marked		N
57.3	Power supply cords		
57.3 a	Equipment not provided with more than one connection to supply mains		P
	Alternative connections to a different supply system do not cause safety hazards when more than one connection is made simultaneously		P
	Mains plug not fitted with more than one power supply cord		P
	Equipment not intended to be permanently connected to fixed wiring is provided with either a power supply cord or an appliance inlet	<i>Appliance inlet.</i>	P
57.3 b	Power supply cords not less robust than ordinary flexible cord, designation 53 of IEC 60245 or IEC 60227	<i>The cord is of type HO3VV-F</i>	P
	PVC insulated power supply cords not used for equipment having external metal parts exceeding 75°C , unless cord rated for the temperature measured	<i>Not applicable. No external metal parts exceeding 75°C</i>	N
57.3 c	Cross-sectional area of power supply cords (see Table XV)	<i>0,75mm² Cu. See list of components. (Data sheet)</i>	P
	Equipment:		
	Initials Tester / Date:		
57.3 d	Stranded conductors fixed by any clamping means or screws are not soldered	<i>Not applicable.</i>	N

57.4	Connection of Power Supply Cords		
57.4 a	Cords anchorages:	<i>Detachable power supply cord used</i>	N
	The equipment or its mains connectors incorporate a cable anchoring device to relieve strain on conductors and prevent abrasion of covering (no knots etc.)		N
	The construction and materials of the cord anchorages are made of insulating material or insulated from unearthed accessible metal parts by supplementary insulation,		N
	or having an insulating lining complying with the requirements for basic insulation fixed to the cord anchorage if an insulation fault on power supply cord could make accessible parts live		N
	Clamping screws do not bear directly on the cord insulation		N
	Screws associated with cable replacement are not used to fix other components		N
	Conductors so arranged that if the cord anchorage fails no strain on protective earth conductor occurs as long as phase conductors are in contact with their terminals		N
	Pull test 25 times		N
	Torque test for 1 min		N
	After the tests, the cord sheath has not been longitudinally displaced by more than 2 mm and the conductor ends have not moved over a distance of more than 1 mm from their normally connected position		N
	Creepage distances and air clearances are not reduced below the values specified in Sub-clause 57.10.		N
	Not possible to push the cord into equipment to such an extent that the cord, or internal parts of the equipment, could be damaged		N
57.4 b	For other than stationary equipment, the power supply cord is adequately protected against excessive bending by means of a cord guard of insulating material		N
	Alternatively shaped opening for the power supply cord		N
	Bending test:		N
	Flexing test (if guards fail the dimensional test) (see IEC 60335-1 AM 6:1988, Sub-clause 25.10)		N
	Results of flexing test:		N
	Percent of broken conductor strands:		N

57.4 c	There is sufficient space inside the equipment to allow the supply cable conductors to be introduced and connected		N
	Any covers can be fitted without risk of damage to the conductors or their insulation		N
	It is possible to check that conductors are correctly connected before the cover is fitted		N
57.5	Mains Terminal Devices and wiring of mains part		
57.5 a	Mains connected equipment other than those with a detachable supply cord is provided with mains terminals, where connections are made with screws, nuts, soldering, clamping, crimping of conductors or equally effective methods	<i>Not applicable. Detachable supply cord used</i>	N
	Reliance not placed upon terminals alone to maintain conductors in position, unless barriers are provided		N
	Terminals of components used for external conductors comply with specified requirements and are properly marked (see 6.2 h, j and k)		N
	Screws and nuts which clamp external conductors are not used to fix any other component (other than internal conductors unlikely to be displaced)		N
	Barriers provided		N
57.5 b	Terminals including any protective earth terminal are closely grouped to allow easy connection		N
	Protective earth conductor, see 58		N
	Marking of mains terminals, see 6.2		N
	Mains terminal devices are inaccessible without the use of a tool		N
	Mains terminal devices are so located or shielded that there is no risk of accidental contact between live parts and accessible conductive parts		N
	- and for class II equipment between live parts and conductive parts separated from accessible parts by supplementary insulation only		N
	Single strand of wire (8 mm). Test result:		N
57.5 c	Tightening or loosening of clamping means of conductors does not subject internal wiring to stress		N
	- does not reduce creepage distances and air clearances below allowable values		N
	Cross-sectional area of the conductor used in the fastening and loosening test:		N

57.5 d	Effective connection to mains terminals does not require special preparation of cables		N
	Conductors are not damaged or displaced when tightening or loosening of clamping screws or nuts		N
57.5 e	Fixing of wiring	See Sub-clause 56.1 f.	P
57.6	Mains Fuses and Over-current Releases		
	List of fuses and over-current releases: See table at the beginning of Clause 56 in this TRF		P
	There are fuses or over-current releases in each supply lead for class I equipment and class II equipment having a functional earth according to Sub-clause 18.1		P
	There is at least one mains fuse for other single phase class II equipment	Class I equipment	N
	A protective earth conductor is not fused		P
	No fuse is fitted in neutral conductor of permanently installed equipment		P
57.8	Wiring of Mains Part		
57.8 a	The insulation of an individual conductor is at least equivalent to that required by IEC 60227 or IEC 60245 (otherwise the conductor is considered bare)	The internal mains wiring has at least the same quality and equivalency to that required in IEC 60227/245.	P
	- dielectric strength test of 2000 V for 1 min		P
57.8 b	The cross-sectional area of internal wiring between the mains terminal and protective devices is not less than minimum required for the power supply cord. Measured area: (see Sub-clause 57.3 c)	Not applicable. Not used	N
	Equipment:		
	Initials Tester / Date:	/	
	The cross-sectional area of other wiring in the mains part and sizes of tracks on printed wiring circuits are sufficient to prevent any fire hazard in case of possible fault currents		N
	In case of doubt concerning adequacy of incorporated overcurrent protection connecting test performed. No safety hazard arises		N
57.9	Mains supply transformers (refer to table below)	See list of components.	
57.9.1	Insulation of mains supply transformers protected against overheating in event of short-circuit or overload (see 57.9.1 a and b)		P
	External protective devices connected such that failure of components cannot render the protective devices inoperative		P

57.9.1 a	Short-circuit test(s) at 90 to 110 percent of rated supply voltage / voltage range				See Nemko ref. No. 200039133. SMP mdoel SNP-8086-M		P
	Supply voltage:						
	Equipment:						
	Initials Tester / Date:						
Winding under test*)					Comments		
T1:							
pin 8-13,14					Shutdown after 1 sec., cycle protection		
pin FL2-10,11,12					Shutdown after 1 sec., cycle protection		
pin 10,11,12-FL1					Shutdown after 1 sec., cycle protection		
	*) Test under the conditions specified in Clause 42.						
57.9.1 b	Overload						
	Tests under the conditions specified in Clause 42 until steady thermal conditions are obtained. Results: See table below.				Temperatures during tests do not exceed values given in Table XIX.		P
	Loading of a section or winding of the transformer:				See Nemko ref. No. 200039133. SMP mdel SNP-8086-M		P
	Supply voltage:				250Vac, 60Hz		
	Equipment:				N3133, N3126, N3636, N3747,N382		
	Initials Tester / Date:				JohnnyG / 09-2000		
Winding under test	Test current max. (A)	Duration (min.)	Δt (°C)	Final t (°C)	Ins. Class B (°C)	Notes	
T1: after D4 (for +5V)	25	124	78	118	175	Unit shutdown, No danger, No damaged	P
T1: after D3 (for +12V)	5,4	130	63	103	175	Unit shutdown, No danger, No damaged	P
OUTPUT OVERLOAD							
For +5V	23	270	66	106	175	Unit shutdown, No danger, No damaged	P
For +12V	5,3	230	60	100	175	Unit shutdown, No danger, No damaged	P

57.9.2	Dielectric strength of electrical insulation between turns and layers			<i>The electrical insulation between primary winding and other windings, screens and the core of the transformer(s) have been investigated by the tests performed as described in Clause 20.</i>			
	Insulation between turns and layers, test performed according to 57.9.2:			<i>Not applicable. SMP used</i>			N
	Voltage used in test:						
	Frequency used in test:						
57.9.4	Construction						
Identification, reference, marking (e.g. T1, T2, etc.)	Manufacturer and type	Total rated power (VA)	Insulation material class	Nominal rated voltages and currents of the windings	General construction*)	Protection devices (manufacturer, type and rating, location)	
<i>Mains transforme. T1</i>	<i>SKYNET (H.K.) Electronic Co. Ltd.</i>		<i>Class B</i>	<i>100-250Vac, 3A</i>			
<i>Inverter transformers: T1, T2</i>	<i>360-8086-M Sen Huei, TRN-0067</i>		<i>Class B</i>				
	<i>TDK SRW15/20EM- T11H004</i>		<i>Class B</i>				
	<i>NIA15/20EM-T11H004</i>		<i>Class B</i>				
*) A construction diagram has to be added to this test report for each transformer mentioned above.							
Drawing							
	<i>See Nemko ref. No 200039133</i>						
Comments	<i>The transformer consists of windings wound on a bobbin with separate integrated forms. The barrier between the primary and secondary windings has a split which increase the distance between them.</i>						
	Creepage distances and air clearances of transformers			<i>See Nemko ref. No 200039133</i>			
Insulation between	Ref. voltage (V)	Air clearance (mm)		Creepage distance (mm)		Notes	
		Required	Measured	Required	Measured		
Primary - Primary	<i>250</i>	<i>1,6</i>	<i>2,1</i>	<i>3,0</i>	<i>3,4</i>	<i>Parts other than windings</i>	
Primary - Secondary	<i>250</i>	<i>5,0</i>	<i>11,5</i>	<i>8,0</i>	<i>11,5</i>	<i>Windings</i>	
57.9.4 a	One of the following methods is used to separate primary from secondary and patient connected windings:			<i>One bobbin with concentric windings separated by double or reinforced insulation</i>			P
57.9.4 c	Means are provided to prevent displacement of end turns						P

57.9.4 d	An earthed screen has a minimum overlap of 3 mm and a width at least equal to the axial length of the primary winding	<i>Not used</i>	N
57.9.4 e	The insulation between the primary and secondary winding in reinforced or double insulated transformers consists of:		P
	number of insulation layer(s):	<i>5 layers</i>	P
	total thickness	<i>0,5mm</i>	P
	combination of two layers withstands dielectric strength test for reinforced insulation	<i>Test voltage 4000Vac</i>	P
57.9.4 f	The creepage distances between the primary and secondary windings comply with requirements for reinforced insulation, with specified allowances	<i>See Sub-clause 57.9.4 e.</i>	P
	mm at location:		P
	Notes:		P
57.9.4 g	For toroidal transformers:	<i>Not applicable. SMP used</i>	
	the exit of wires from internal windings is provided with double sleeving complying with requirements for double insulation		N
	its total thickness is at least 0.3 mm extending at least 20 mm outside the winding. Measured thickness:		N

57.10	Creepage distances and air clearance						
57.10 a	Values (refer to table)						
	Creepage distances and air clearances comply at least with the values of Table XVI						P
	Creepage distances for slot insulation of motors are at least 50% of the values in the table with a minimum of 2 mm at 250 V			No motor used			N
	Creepage distances and air clearances between defibrillation proof applied parts and other parts are not less than 4 mm			No defibrillation proof applied parts			N
	Insulation between	Ref. voltage (V)	Air clearance (mm)		Creepage distance (mm)		Notes
			Required	Measured	Required	Measured	
Equivalent to basic insulation between parts of opposite polarity	A - f	250	1,6	4,6	3,0	4,6	
Basic or supplementary insulation	A - a ₁						
	A - b						
	A - c						
	A - j						
	B - d						
	B - c						
Double insulation or reinforced insulation	A - a ₂	250	5,0	12,3	8,0	25,0	
	A - e	250	5,0	25,0	8,0	35,0	
	A - k	250	5,0	7,0	8,0	12,4	
	B - a	250	5,0	7,0	8,0	8,6	
	B - e						
Comments							
57.10 b	Statements , test specifications etc. observed						
57.10 d	Statements regarding measurement of creepage distances and clearances observed						

58	PROTECTIVE EARTHING -TERMINALS AND CONNECTIONS		
58.1	Clamping means of the protective earth terminal for fixed supply conductors or power supply cords comply with requirements of Sub-clause 57.5 c:		P
	Not possible to loosen the clamping means without use of a tool		P
	Screws for internal protective earth connections are covered or protected against loosening from outside		P
58.2	Internal protective earthing connections by means of screw, soldering, crimping, wrapping, welding or a reliable pressure contact		P
58.3	Not used (see 57.5 b)		
58.7	Where an appliance inlet is used for the supply connection, its earth pin is regarded as the protective earth terminal		P
58.8	The protective earth terminal is not used for connection between different parts or fixing of any component not related to protective or functional earthing		P
58.9	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting		P

59	CONSTRUCTION AND LAYOUT		
59.1	Internal wiring		
	Fixing of wiring in the applied part and the mains part, see Sub-clause 56.1 f	<i>Not applicable. No applied part</i>	N
59.1 a	Internal cables and wiring:		
	- are protected against contact with moving parts and friction with sharp corners and edges	<i>No moving parts. The wiring is adequately protected against sharp edges etc.</i>	N
	- are protected by additional fixed sleeving or similar means , if there is movement relative to metal parts where it is in direct contact with metal parts		N
	- and wiring , cord forms or components are not likely to be damaged by opening or assembling the equipment or opening or closing of inspection doors		P

59.1 b	The bending radius of cables and cable forms is at least 5 times the outer diameter of the lead	<i>Not applicable.</i>	N
59.1 c	Insulation:		
	- insulating sleeving is adequately secured. It can only be removed by breaking or cutting or is secured at both ends		P
	Sheath of a flexible cord used as supplementary insulation inside equipment is not subject to undue mechanical or thermal stresses and its insulation properties are at least as specified in IEC 60227 or IEC 60245	<i>Not applicable.</i>	N
	- insulated conductors, which are subject to temperatures greater than 70°C, have an insulation of heat-resistant material	<i>Not applicable. No temp over 70 deg.C</i>	N
	Dielectric strength test of insulation of 2000 V for 1 min		N
59.1 d	Aluminium wires below 16 mm ² cross-section are not used	<i>Not used</i>	N
59.1 e	Separation of circuits (see Clause 17)		
59.1 f	Connecting cords between equipment parts (e.g. parts of an x-ray or patient monitoring installation or a data-processing installation or combinations) are considered belonging to equipment and subject to requirements of this standard	<i>Not applicable. No such connection</i>	N
59.2	Insulation		
59.2 b	Insulation characteristics, mechanical strength and resistance to heat and fire is retained. Result of the ball-pressure test:	<i>Test of enclosure parts. Temperature of ball 90 °C. d=1.3mm</i>	P
59.2 c	Insulation is not likely to be impaired by deposition of dirt or dust resulting from wear of parts within the equipment such that creepage distances and clearances are reduced below specified values		P
	Ceramic materials and the like specified in this sub-clause are not used as supplementary or reinforced insulation	<i>Not used</i>	N
	Rubber materials used as supplementary insulation in class II equipment are resistant to ageing (oxygen test) and arranged and dimensioned adequately	<i>Class I equipmet</i>	N
	Creepage distances are not reduced below values specified in 57.10 despite any cracks in such insulation		P

	Insulating materials in which heating elements are embedded are not used as reinforced insulation	<i>No heating elements used</i>	N
59.3	Excessive current and voltage protection		
	See Sub-clause 57.6. An internal electrical power source in equipment is provided with an appropriately rated device to protect against fire hazards. Protective means used. Inspection of design data	<i>No internal electrical power source</i>	N
	Fuse elements replaceable without opening the enclosure are fully enclosed in a fuseholder and fuse replacement does not cause safety hazard. Test with standard test finger.	<i>Not applicable. Must open the enclosure</i>	N
	Live parts of fuseholders are shielded to prevent electric shock when replacing fuses (if replaceable without the use of a tool)	<i>See above</i>	N
	Protective devices between an F-type applied part and the enclosure do not operate below 500 V r.m.s.	<i>Not applicable. No F-type applied part</i>	N
59.4	Oil containers		
	Oil containers in portable equipment are adequately sealed to prevent oil loss in any position and the oil container design allows for the expansion of oil	<i>Not applicable. No oil containers used</i>	N
	Oil containers in mobile equipment are sealed to prevent loss of oil during transport		N
	An oil level indicator is provided on partially sealed oil-filled equipment or parts. Inspection of equipment and technical description , and by manual test		N

The schematic diagram illustrates the electrical architecture of the test bench. It features two main power input sections at the top, both connected to a 'Réseau Mains' (Main Network) with L(N) and N(L) terminals.

- Top Section:** Includes transformer T2, voltmeter V2, switch S9, and a pump P1. A circled number 3 indicates a specific component or connection point.
- Bottom Section:** Includes transformer T1, voltmeter V1, switches S1, S5, S7, S10, and S12. It also features two pumps, P1 and P3, and two motor units, MD1 and MD2. The bottom section is grounded.

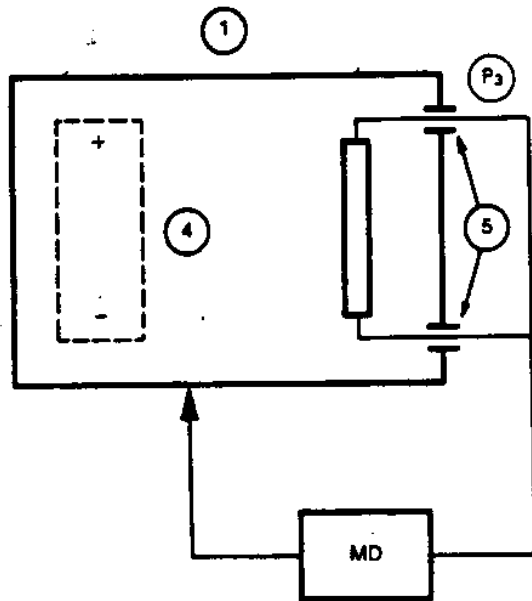
The diagram shows various interconnections between these components, including wiring paths for the pumps (P1, P3), motors (MD1, MD2), and control elements like switches and transformers. Specific points are labeled FE and PE, likely representing fluid entry and exit or pressure measurement points.

¹ and ² = Before and after humidity preconditioning treatment.				
Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above

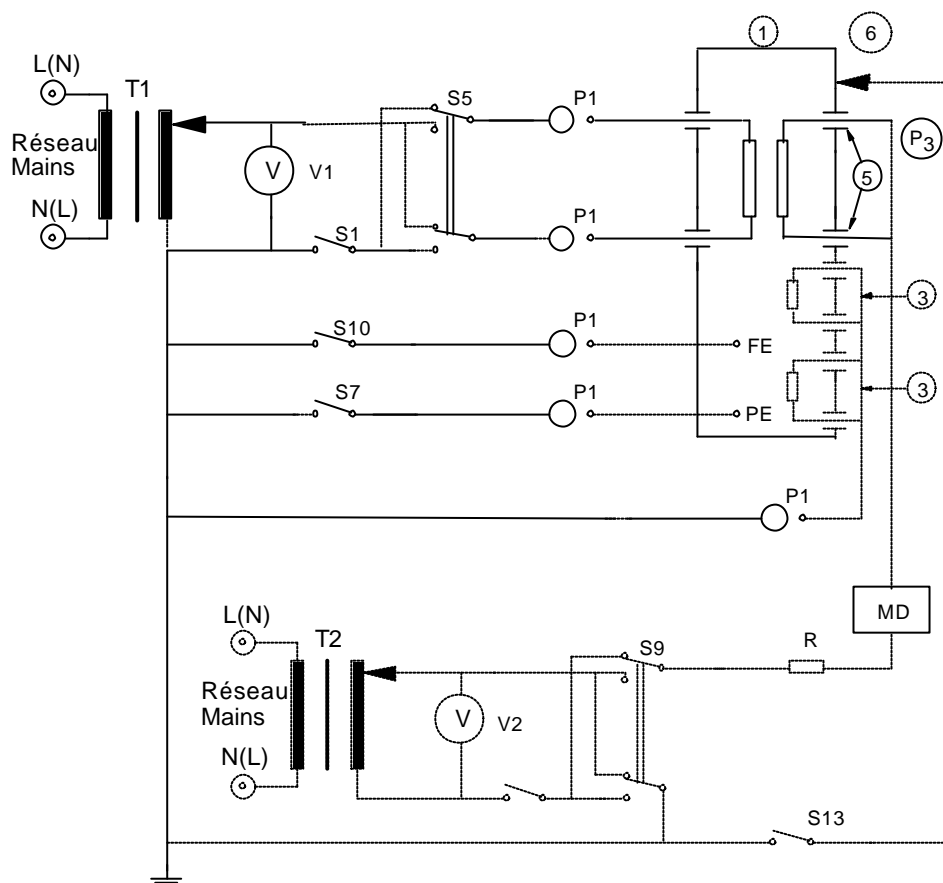
19.4 g	APPENDIX 2			
Fig. 18 in IEC 60601-1	Measurement of the enclosure leakage current	FOR INTERNALLY POWERED EQUIPMENT		N
<div>See fig. 18 on previous page.</div> <div>Using MD2 between different parts of the enclosure.</div>				
Normal Condition Measured (µA)				
Before ¹		After ²		
Comments :				
¹ and ² = Before and after humidity preconditioning treatment.				

Le schéma illustre la configuration électrique d'un tableau de distribution. À l'entrée, un transformateur T1 (Réseau Mains) est connecté aux bornes L(N) et N(L). Le tableau est divisé en deux sections principales. La section supérieure contient des interrupteurs S1, S5, S10, S7, et S13, ainsi qu'un moteur MD. Les bornes P1, P3, FE, PE, et PE sont indiquées. Des numéros 1, 5, et 6 sont placés dans des cercles.

¹ and ² = Before and after humidity preconditioning treatment.				
Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above

19.4 h	APPENDIX 3		
Fig. 23 in IEC 60601-1	Measurement of the patient leakage current	FOR INTERNALLY POWERED EQUIPMENT	N
<div></div>			
Normal Condition Measured (µA)			
Before ¹		After ²	
Comments :			
¹ and ² = Before and after humidity preconditioning treatment.			

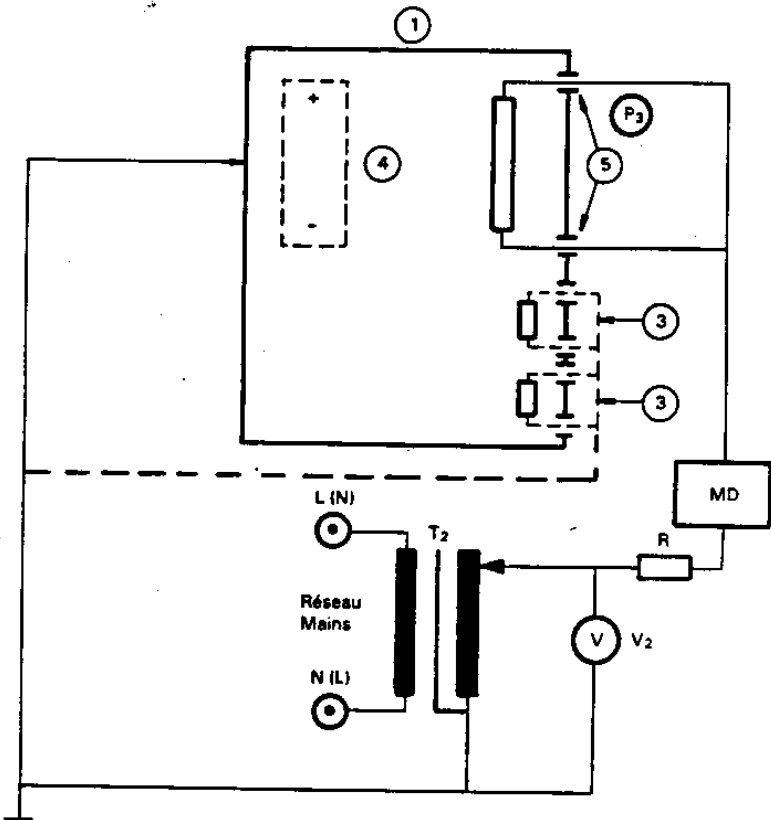
19.4 h2	APPENDIX 4		
Fig. 21 in IEC 60601-1	Measurement of the patient leakage current with mains voltage on the f-type isolated (floating) applied part	FOR MAINS OPERATED EQUIPMENT	N



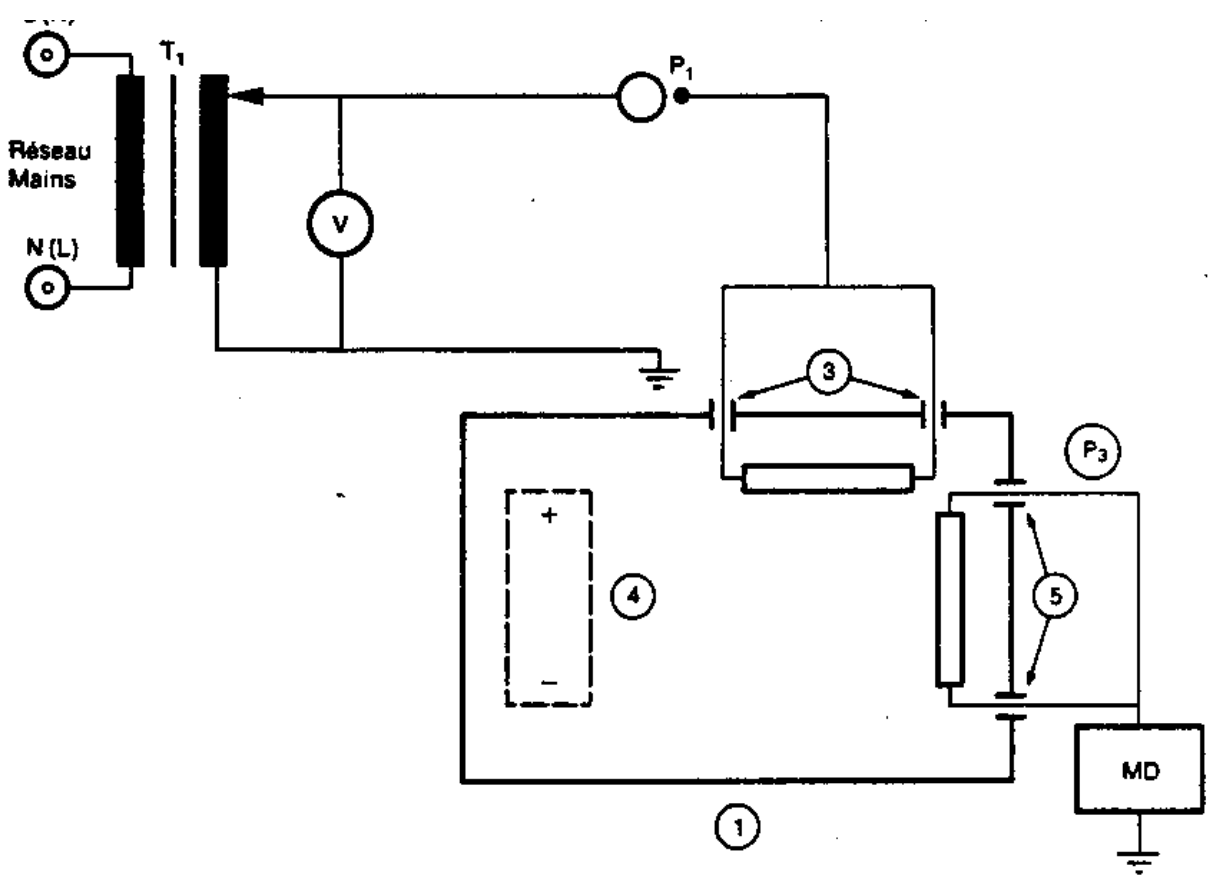
Switch position			Measured μA	
S5	S10	S13	Before ¹	After ²
1	1	1	—	—
1	1	0	—	—
1	0	1	—	—
1	0	0	—	—
0	1	1	—	—
0	1	0	—	—
0	0	1	—	—
0	0	0	—	—

¹ and ² = Before and after humidity preconditioning treatment.

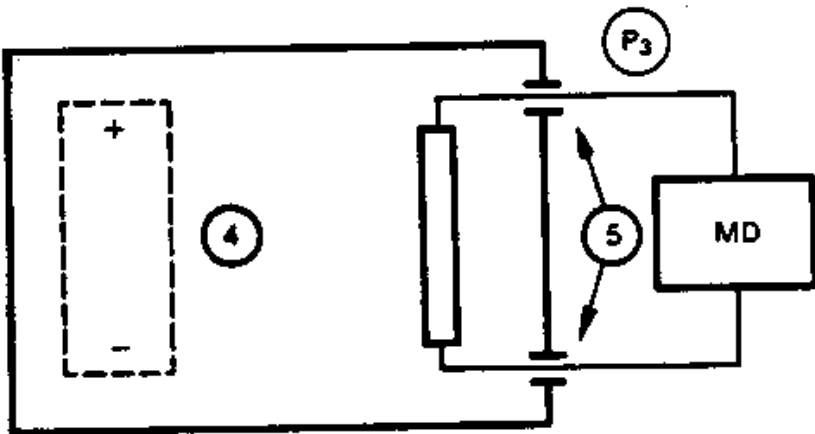
Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open
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19.4 h2	APPENDIX 4		
Fig. 24 in IEC 60601-1	Measurement of the patient leakage current with mains voltage on the f-type isolated (floating) applied part	FOR INTERNALLY POWERED EQUIPMENT	N
<div></div>			
Single Fault Condition Measured (µA)			
Before ¹		After ²	
Comments :			
¹ and ² = Before and after humidity preconditioning treatment.			

19.4 h3		APPENDIX 5			
Fig. 22 in IEC 60601-1		Measurement of the patient leakage current with mains voltage on a signal input or signal output part	FOR MAINS OPERATED EQUIPMENT	P	
<div></div>					
					Switch position
S5	S10	S13	Before ¹	After ²	
1	1	1	113	113	
1	1	0	113	113	
1	0	1	—	—	
1	0	0			
0	1	1	113	113	
0	1	0	113	113	
0	0	1	—	—	
0	0	0			
¹ and ² = Before and after humidity preconditioning treatment.					
Note:	S7 not used for Class II equipment		NC = Normal Conditions SFC = Single Fault Condition		1 = Switch Closed 0 = Switch Open

19.4 h3	APPENDIX 5		
Fig. 25 in IEC 60601-1	Measurement of the patient leakage current with mains voltage on a signal input or signal output part	FOR INTERNALLY POWERED EQUIPMENT	N
<div></div>			
Single Fault Condition Measured (µA)			
Before ¹		After ²	
Comments :			
¹ and ² = Before and after humidity preconditioning treatment.			

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19.4 j	APPENDIX 6		
Fig. 27 in IEC 60601 -1	Measurement of the patient auxiliary current	FOR INTERNALLY POWERED EQUIPMENT	N
<div></div>			
Normal Condition Measured (µA)			
Before ¹		After ²	
Comments :			
¹ and ² = Before and after humidity preconditioning treatment.			